

**Investigating the effectiveness of COVID-19 testing choices, community engagement,  
and culturally-embedded mHealth literacy delivery in a medically-underserved,  
community-based sample**

**UIC Principal Investigator:**

UIC College of Medicine

**UIC Co-Principal Investigator**

UIC College of Applied Health Sciences

**Co-Investigators**

Mile Square Health Center

UIC School of Public Health

**Study Location(s):**

UI Health Clinical Microbiology Laboratory, 840 South Wood Street Chicago, IL 60612  
University of Chicago Medicine, Department of Obstetrics and Gynecology, 5841 S. Maryland Ave., Chicago, IL 60637

UIC College of Applied Health Sciences, 1919 W. Ismail St. (MC 811), Third Floor, Chicago, IL 60612

UIC School of Public Health, 955 SPHPI, MC 923, Chicago, IL 60612

Mile Square Health Center Main, 1220 South Wood Street Chicago, IL 60608

UI Health Acute Care, 1220 South Wood Street Chicago, IL 60608

UI Health Mile Square Health Clinic Back of the Yards, 4630 South Bishop Street Chicago, IL 60609

UI Health Mile Square Health Clinic Cicero, Hawthorne Works Shopping Center 4745–51 West Cermak Road Cicero, IL 60804

UI Health Mile Square Health Clinic Englewood, 641 W. 63rd St. Chicago, IL 60621

UI Health Mile Square Health Clinic Humboldt Park, 3240 West Division Street Chicago, Illinois 60651-2405

UI Health Mile Square Health Clinic South Shore, 7037 S. Stony Island Ave. Chicago, IL 60649

UI Health Hope Institute Learning Academy Health and Wellness Center, 1628 West Washington Boulevard Chicago, IL 60612

UI Health National Teachers Academy Health Center, 55 West Cermak Road Chicago, IL 60616

UI Health Davis Health and Wellness Center, 3050 West 39th Place Chicago, IL 60632

UI Health Young Women's Leadership Charter School Clinic 2641 South Calumet Avenue Chicago, IL 60616

UI Health Englewood Health and Wellness Center, 6835 S Normal Blvd, Chicago, IL 60621

UI Health Dr. Cynthia Barnes-Boyd Health and Wellness Center, 2710 S. Dearborn St. Chicago, IL 60616

Mile Square Health Center – L.P. Johnson Rockford 1221 E. State St. Rockford, IL 61104

Community Sites:

*Southeast Side of Chicago Food Pantry, 11401 S Green Bay Ave, Chicago, IL 60617*

*One Health Englewood, 144 W 71 Place. Chicago, Illinois 60636*

*It takes a Village Family of Schools, 806 N. Peoria Street. Chicago, IL, 60642.*

*Mobile Care Chicago, 239 W. Root Street, Chicago IL 60609.*

*LULAC of Cicero, 1913 S. 55th Ct., Cicero, IL 60804*

**Sponsor:** National Institutes of Health, Program Administrator  
Genes, Environment, and Health Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences  
P.O. Box 12233 (MD EC-21)  
Research Triangle Park, NC 27709

**Version:** 6.0

**Date:** July 1, 2021

## **LIST OF ABBREVIATIONS**

FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
mHealth	Mobile Health
MSHC	Mile Square Health Center
OPRS	Office of the Protection of Research Subjects
PHI	Protected Health Information
PI	Principal Investigator
SAE	Serious Adverse Event
SOP	Standard Operating Procedure

## 1.0 PROJECT SUMMARY/ABSTRACT

This project will employ sentinel and community-based epidemiological surveillance and participatory research methods to evaluate whether a person-centered, rapid COVID-19 testing intervention (at-home swab and send, or on-site point of care testing), coupled with a novel mHealth COVID-19 Literacy and Outreach Suite of apps and videos, will serve to increase the acceptance, access, reach, uptake, and impact of COVID-19 testing at UI Health and in the 14 FQHC practice sites and their corresponding catchment areas. We will also analyze the social, ethical, economic, and behavioral drivers and consequences of our outreach and testing approaches according to the degree to which participants contribute to the co-creation of study-related messaging. Finally, we will leverage our existing infrastructures to expand testing uptake and analyze (by PCR) viral load at infection onset/exposure and following onset/exposure to determine viral dynamics and identify individuals at early and late stages of infection. NIH PhenX self-report measures will be used to test intervention effects on testing and retesting uptake, time-to-diagnosis, COVID-19 knowledge, healthcare access and seeking, disclosure, medical adherence, and practice of home self-isolation, quarantine, and other infection control behaviors. All data acquisition, collection and curation approaches will be informed by the CDCC, including AboutML-informed consent approaches and with the other RADxUP studies and relevant federal agencies. The central hypothesis of this study argues that a persuasive mHealth Suite of apps and videos (yet to be co-created with community members) combined with person-centered COVID-19 testing choices (remote at home nasal swab versus on-site nasal swab), will lead to higher COVID-19 testing uptake in 7000 adults and children living in the geographic catchment areas of the 14 Mile Square Health Center practice sites (as compared with baseline rates of testing uptake in the same geographic catchment area). This relationship will be mediated by a number of social, economic, and behavioral determinants of health, including self-reported COVID-19-related knowledge, COVID-19 social capital, COVID-19 racial/ethnic bias and stigma, and COVID-19 preventative and risk behaviors. (Any analysis of mediators will be limited to the adult sample). This will be accomplished utilizing a repeated measures, pre-post-test mediational design. Interviews will be conducted over the phone on Day 1 and Day 28 of a 28-day study period, to track outcomes. With improved access to testing and care, self-management strategies of COVID-19 and increased knowledge, a higher percentage of people living in underserved neighborhoods will have access to testing and necessary follow-up care and are expected to develop a stronger sense of empowerment over their own healthcare decisions related to COVID-19.

THREE GROUPS WILL BE RECRUITED TO PARTICIPATE IN THIS STUDY (SEE FIGURE 1 BELOW). THE FIRST GROUP WILL BE RECRUITED FROM THE 14 MILE SQUARE HEALTH CENTER (MSHC) PRACTICE SITES. THE SECOND GROUP WILL BE RECRUITED THROUGH CONTACT TRACING OF COVID-19 TEST POSITIVES FROM MSHC. THE THIRD GROUP WILL BE RECRUITED FROM THE COMMUNITY THROUGH POSTED STUDY ADS AND FLYERS ONLINE, WHICH WILL FIRST CONTAIN THE STUDY CONTACT NUMBER AND EVENTUALLY WILL CONTAIN AN INVITATION TO FIND OUT ABOUT THE STUDY THROUGH THE MOBILE HEALTH (MHEALTH) SUITE OF APPS AND VIDEOS. IN ADDITION TO NASAL SWAB TESTING FOR COVID-19, PARTICIPANTS WILL HAVE ACCESS TO SMARTPHONE APPS TO TRACK SYMPTOMS, IMPROVE KNOWLEDGE OF COVID-19, AND LEARN SELF-MANAGEMENT SKILLS WHILE AT HOME. ONE NASAL SWAB SAMPLES WILL BE COLLECTED (ON-SITE OR AT HOME).. PARTICIPANTS WHO ARE NOT INITIALLY IDENTIFIED VIA A CALL OR IN-PERSON VISIT TO MILE SQUARE HEALTH CLINIC WILL HAVE THE OPPORTUNITY TO PARTAKE IN RAPID, COVID-19 NASAL SWAB SELF-COLLECTION AT HOME. RESEARCH MEMBERS WILL SHARE THE DATA COLLECTED FROM THE BIOLOGICAL SPECIMENS, INTERVIEWS, AND APPS WITH THE ILLINOIS DEPARTMENT OF PUBLIC HEALTH. THE FINAL GOAL OF THIS STUDY WILL BE PREVENTION OF COVID-19 TRANSMISSION THROUGH INCREASED COVID-19 LITERACY AND EMPOWERMENT, COMBINED WITH EARLY INTERVENTION VIA RAPID DIAGNOSIS, CONTACT TRACING, AND EARLIER ACCESS TO TREATMENT. 2.0

## BACKGROUND/SCIENTIFIC RATIONALE

Since the first U.S. cases were identified in Washington on January 20th and soon thereafter in Chicago on January 24th, COVID-19 has rapidly emerged as the most prevalent and deadly respiratory infection within the State of Illinois, with 220,178 total confirmed cases and 7,880 (3.6%) deaths. The UIC Hospital and Health Care System (UI Health), in collaboration with its 14 partnering Federally Qualified Mile Square Health Center practice sites (FQHCs) (where this project will be implemented), saw over 4,000 of these cases between March and June, 2020 (6), noting the disproportionately higher rates of COVID-19 in Latinx people (47.1% with 32.7% of deaths) and in people identifying as African American or Black (28.9% with 43.1% of deaths). Of 48,111 cases reported in Cook County alone, 7,231 (15.0%) were hospitalized with 2,234 (4.6%) in an intensive care unit. These COVID-19-related morbidity and mortality disparities are accompanied by numerous other health disparities. Many of our FQHCs lack the staffing and revenue to test on-site and provide extensive follow-up outpatient care for the large influxes of symptomatic patients concerned about COVID-19. These challenges have likely resulted in increased COVID-19-related complications and deaths that might have been prevented with clearer and more accurate public messaging about COVID-19, wider access to testing, earlier diagnosis, and an increased perception that care is confidential, accessible, and self-driven.

### 3.0 Objectives/Aims

We will leverage our university-community partnerships and robust clinical microbiology and epidemiological infrastructures to collaborate with our 14 UI Health FQHCs to expand access to rapid, FDA-approved COVID-19 testing. The COVID-19 Unit of the Center for Biostatistical Development will confidentially and securely collect, integrate, store, and share all personally-identified, molecular test results and self-report PhenX data to conform to the NIH Coordination and Data Collection Center (CDCC) common data elements. The Microbiology Laboratory will oversee the testing expansion, data analysis, and storage of all specimens in preparation for any future break-the-glass requests. We will utilize AboutML-informed consent approaches and share all findings with the other RADxUP studies and with the relevant federal agencies.

**Aim 1:** Combine sentinel and community-based surveillance approaches and a culturally-embedded COVID-19 mHealth Literacy and Outreach Suite to increase acceptance, access, reach, uptake, and impact of rapid nasal swab testing in 7,000 vulnerable children and adults living in the catchment areas of the 14 FQHCs.

Sub-aim 1.1: a) Estimate baseline rates of testing uptake in the 14 catchment areas. b) Administer a testing and mHealth intervention that offers two collection and results-delivery choices (on-site nasal swab tested with 15-30-minute point of care test versus nasal self-swab and send tested with standard molecular test with 24-hour sample to result time). c) Examine PhenX-defined determinants of health (COVID-19 knowledge, social capital, racial/ethnic stigma, risk & preventative behaviors) as mediators of testing uptake in the adult intervention sample. d) Further disaggregate the sample of those tested according to collection & results-



delivery choice in a comparative-effectiveness analysis of willingness to retest and testing satisfaction.

Sub-aim 1.2: a) Increase frequency of testing of asymptomatic and symptomatic individuals to monitor viral dynamics during course of infection. b) For test-positives, administer PhenX social-determinants measures on Day 28 to assess the effects of the testing and mHealth intervention on retesting uptake, time-to-diagnosis, healthcare seeking, COVID-19 disclosure, medical adherence, home self-isolation and public self-quarantine, and other infection control parameters. c) Assess the impact of testing positive using the PhenX Impact of COVID-19 on Behavior: Stress, Anxiety, Food or Economic Insecurity, and Mental Health measure.

**Aim 2:** Apply participatory methods to analyze the social, ethical, economic, and behavioral drivers and consequences (barriers and facilitators) of our outreach and testing approaches.

Sub-aim 2.1: a) Expand community-based testing by engagement of community champions. These partners will co-create and distribute project-related social media, radio, and community-TV advertisements, COVID-19 literacy flyers and posters, and the culturally-embedded and multilingual mHealth COVID-19 Literacy & Outreach Suite, and b) identify high-risk congregate settings in which swab and send testing kits will be made freely available by study staff, in agreement with setting managers/proprietors.

Sub-Aim 2.2: Compare the 300 community champion participants with the other 7,000 study participants to assess the effects of participatory action on PhenX-defined COVID-19 knowledge and PhenX-defined COVID-19 social capital. Based on advances in empowerment theory, we hypothesize that COVID-19 knowledge and social capital will increase as a result of co-creating and disseminating study ads, locating high-risk congregate settings for testing kit distribution, and co-constructing the mHealth Literacy and Outreach Suite.

#### **4.0 Eligibility**

This study will include non-decisionally impaired adults and children age 7 years and older, all sexes-at-birth, all gender identifications, races, ethnicities, income levels, and educational status living in Cook County or Suburban Cook County within the State of Illinois. Subjects may have any type of pre-existing health conditions, including pregnancy, and may or may not have COVID-19- related exposure or symptoms.

Three groups will be recruited to participate in this study (see Figure 1). The first group will be recruited from the 14 UI Health Mile Square Health Center (MSHC) practice sites. The second group will be recruited through contact tracing of the COVID-19 test positives from MSHC. The third group will be recruited from the community through posted study ads and flyers online, which will first contain the study contact number and eventually will contain an invitation to find out about the study through the mobile health (mHealth) suite of apps and videos.

Subject eligibility will be assessed and determined by one of three approaches: (1) by one of 13 study-trained nurse or nurse practitioner/MSHC health care staff who consents and enrolls subjects at one of the 13 Mile Square Health Center practice sites, (2) by an undergraduate or

graduate student research assistant who responds to a call to the study telephone number, or (3) through the enrollment app within the suite of apps and interviews used for the study.

Eligibility will be documented using the following Chicago DADx-UP Eligibility and Survey Questionnaire.

Eligibility Questionnaire (also provided in Spanish)

Subject Phone Number \_\_\_\_\_

Subject ID Number \_\_\_\_\_

1) Do you live in the State of Illinois within Chicago or Suburban Cook County?

Yes \_\_\_\_\_

No \_\_\_\_\_

2) Do you speak (or read) English or Spanish?

Yes \_\_\_\_\_

No \_\_\_\_\_

3) Are you over the age of 18?

Yes \_\_\_\_\_

No \_\_\_\_\_ (parental approval or approval of a legally authorized guardian or guardian ad litem must be granted before participation - utilize parental consent and child assent form)

4) For Adults over the age of 18: Are you able to make your own health care decisions or do you have a legal guardian who does this for you?

Yes, I am able to make my own health care decisions \_\_\_\_\_

No, I am not able to make my own health care decisions \_\_\_\_\_

*Note: Only those responding "yes" to questions 1, 2, and 4 are eligible to participate in this study. For those answering no to question 3, parental verbal approval and signature on the parental consent form, along with child assent and signature on the child assent form (where applicable) must be granted before study participation.*

Eligibility Questionnaire – Child Version (also provided in Spanish)

Parent's Phone Number \_\_\_\_\_

Subject ID \_\_\_\_\_

1) Does your child live in the State of Illinois within Chicago or Suburban Cook County?

Yes \_\_\_\_\_

No \_\_\_\_\_

2) Do you/your child speak (or read) English or Spanish?

Yes \_\_\_\_\_

No \_\_\_\_\_

3) Is your child over the age of 18?

Yes \_\_\_\_\_ (use adult consent form and process)

No \_\_\_\_\_

*Note: Only those responding “yes” to questions 1 and 2 are eligible to participate in this study.*

#### **4.1 Inclusion Criteria**

1. Human subjects identifying as any sex or gender, of any race, ethnicity, or national origin, ages 2 and above.
2. Subjects must self-report on the eligibility questionnaire that they reside in Cook County or Suburban Cook County.
3. Asymptomatic individuals seeking testing for any reason or symptomatic individuals presenting with any multi-system symptom or sign suggestive of COVID-19 or infectious disease (e.g., fever, rashes, malaise, headache, myalgia, vomiting, diarrhea, or cough).
4. Any individual reporting exposure to a COVID-19 positive person or someone suspected as having COVID-19.
5. Any individual with a travel history to another COVID-19 hot spot or any individual reporting presence in any local high-risk congregate setting.
6. Any individual with any diagnostic comorbidity or condition including, but not limited to, obesity, cancer, diabetes, cardiovascular heart disease, hyperlipidemia, systemic lupus erythematosus or rheumatologic disease, positive HIV/AIDS, and/or any current medications such as anti-inflammatory medications including corticosteroids.
7. Any individual speaking or reading English or Spanish will be included.
8. Homeless individuals who seek care at one of the 13 Mile Square Federally Qualified Health Center practice sites.

#### **4.2 Exclusion Criteria**

1. Any individual residing outside of Cook, Suburban Cook, and Winnebago Counties will be excluded.
2. Any person speaking a language for which translation services are not available through UI Health at the time of enrollment. Typically, language translation services are available for a wide

range of languages, but services are not always available in all languages during times of heavy demand.

#### **4.3 Excluded or Vulnerable Populations**

The study aims to include economically and/or educationally underserved and vulnerable individuals because the aims of this study are consistent with the mission of UIC and UI Health. As an FQHC, UI Health MSHC provides services to approximately 40,000 underserved persons in the Chicago Metropolitan Area. Being that potential subjects will be identified through UI Health and other community-based organizations in the area, it is necessary to include individuals who are economically and/or educationally disadvantaged. Increasing their knowledge of COVID-19, providing access to testing, and increasing their self-care agency could fill a critical **missing gap** in reducing COVID-19 transmission, morbidity, and mortality for this population. It is also important to study transmission dynamics of the virus, especially in underserved communities that include a high density of Black/African American and Latinx adults and children, who are at increased risk for exposure and susceptibility to severe disease.

Decisional impaired adults will be excluded from the study because they are a vulnerable population that is unable to complete the necessary requirements of the study for adult participants (i.e., increasing COVID-19 knowledge via interaction with the mHealth apps and videos). People speaking languages other than English or Spanish will be excluded from the study due to lack of resources and the pre-existing mobile apps being used for this study primarily being written in English and Spanish.

The rationale for excluding those living outside Cook, Suburban Cook, and Winnebago Counties involves our study design. We are comparing baseline rates of testing uptake in Cook and Suburban Cook Counties with testing uptake in the same areas following the testing and mHealth intervention. Including individuals outside of these catchment areas would prevent accurate statistical comparisons for outcomes related to testing uptake, case positivity, and deaths, archived by the Illinois Department of Public Health.

#### **5.0 Subject Enrollment**

Outside of the questions included in the eligibility questionnaire described in Section 4.0, subjects will not be screened in order to participate in the study. Subjects will be introduced to the study in any of the following ways: (1) in person when they are seeking care at one of the Mile Square Health Center practice sites, (2) over the phone when contacting the Mile Square Health Center practice sites to inquire about COVID-19 or participating in a telehealth visit, (3) when responding to a study advertisement by calling the study telephone number after viewing a study flyer, electronically based ads, or through learning about the study from community based organizations, or (4) by enrolling in the mHealth component of the study through the Enrollment App (to be developed) within the COVID-19 Literacy & Outreach Suite. Following completion of the eligibility questions during an in-person or telephone interview, subjects will be consented and enrolled according to one of the four ways just described.

(1) An on-site nurse or nurse practitioner or other MSHC healthcare professional will consent and enroll the subject in person using a paper consent form during a usual care visit to the practice site. The paper consent form (or parental consent and child assent) will be hand-delivered to the lab of the PI by a study courier during regularly scheduled pick-ups at the practice sites.

(2) A remote (telephone or telehealth) nurse or nurse practitioner or other MSHC healthcare professional will consent and enroll the subject via phone and a digital version of the adult consent form (or parental consent and child assent), presented digitally for subject signature through a RedCap database.

(3) The PI or an undergraduate or graduate research assistant will consent and enroll the subject via phone and the same digital version of the adult consent form (or parental consent and child assent), presented digitally for subject signature through a RedCap database.

(4) The Enrollment App will: (a) guide them through an attenuated consent and enrollment process that only covers their interaction with the apps and videos within the mHealth COVID-19 Literacy & Outreach Suite. Based on subjects' responses to the symptoms questions and exposure questions in the Stoplight and Group Settings apps, an automated text message may prompt the subject to contact the study phone number for additional consent and enrollment to obtain COVID-19 testing, and to participate in the telephone interviews.

**Recruitment and Recruitment Materials** Subjects will be identified via one of three epidemiological surveillance approaches. Group 1 subjects (sentinel surveillance) will be initially identified through the 14 FQHC-MSHC practice sites, including school-based clinics, presenting for care due to one or more symptoms suggestive of COVID-19 either over the phone or in person at the clinic. Group 2 (n=750) will be identified via contact tracing from those in contact with members of group 1. Group 3 (n=5,250) will be identified by distributing digital ads and paper flyers in congregate settings and highly trafficked areas throughout Chicagoland and Suburban Cook Counties. We will use our social networks to promote the study via local religious leaders, store owners, educational leaders and other community organizers with whom our team has longstanding and strong relationships in the City of Chicago. Correspondingly, participants will find out about the study in one of the following ways: via study flyer or digital advertisement, recruited by a nurse or nurse practitioner or other healthcare professional when the subject visits or contacts one of the 13 MSHC practice sites, or recruited when they locate and upload the mHealth COVID-19 Literacy and Outreach Suite (directions on how to locate and upload the Suite will be included in study advertising).

During Months 2 - 22 of the one-year study period, we will utilize three epidemiological surveillance approaches to recruit the anticipated sample of 7000 children and adults. For the first surveillance approach, we will recruit an expected sample of 1000 children adults who are seeking care from one of the 13 UI Health Mile Square practice sites. These individuals will be invited to participate if they present in person or by telephone with symptoms suggestive of any

infectious illness, including COVID-19. They will be provided with a digital link that will be texted to the prospective participant (if calling by telephone) or provided via a paper handout (if visiting the site) containing an ad about the study, including information about how to consent and enroll in the study (See Recruitment Ad here:

<https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:eb5536a2-adeb-489e-942e-cea4d99055b2>). The historical-average positivity rate of COVID-19 within Chicago is 9.79% and 8.68% in Cook County. Given these rates, it is estimated that approximately 94 of 1,000 enrollees will test COVID-19 positive in Group 1. Contact tracing of the 94 test-positives from Group 1 represents the second surveillance approach. Group 2 will be recruited with a digital link to the recruitment ad that will be texted to the prospective participant, who will be identified by contact tracing of the Group 1 participants testing positive for COVID-19. The Chicago Department of Public Health defines contact tracing as ‘involving interviewing a person who has tested positive for the disease (the “index patient”) to create a list with whom the index patient was in close contact (within 6 feet) for more than 15 minutes, starting from 48 hours before illness onset.’ CDC’s CovidTracer 1.0 spreadsheet-based tool provides 5 – 20 as an illustrative range for contacts per case whereas estimates of the basic and effective reproduction numbers (expected number of infections from one case)  $R_0$ , and  $R_e$  vary between 2.0 to 5.7 in the literature. Based on conservative estimates, 8 contacts per case and ~750 additional persons who are contact-traced for the estimated 94 test positives from Group 1. The third recruitment approach is community-based surveillance. Group 3 will be recruited via the Recruitment Ad, which will be disseminated digitally by all key personnel via UI Health-linked and UIC-linked social media accounts and disseminated by paper handouts placed with consent of managers or owners of local businesses, religious places of worship, pharmacies, grocery stores, other health centers, and community based organizations located throughout the 14 geographic catchment areas served by the 14 Mile Square Health Center practice sites. It is estimated that approximately 508 of 5,500 enrollees will test COVID-19 positive in this group.

These Group 3 individuals will also undergo the same testing and mHealth procedures and will be invited and enrolled during Months 2–22. It is estimated that approximately 508 of 5,500 enrollees will test COVID-19 positive in this group.

**Ineligible Subjects:** There will be no screen failures as subjects will not be screened in order to participate in this study. Those who do not meet eligibility criteria according to the eligibility questionnaire will be informed of their ineligibility immediately during the in-person or telephone eligibility interview or via the app, which will not advance if the person does not self-report “yes” to the eligibility criteria. The eligibility questionnaires will be stored separately from all other data in a locked file cabinet in the PI’s locked office, or, if digitally collected, in a separate encrypted RedCap database

**Methods to Minimize Coercion and Undue Influence:** Participants seeking diagnostic testing for COVID-19 at one of the 14 MSHC practice sites will receive testing, irrespective of whether they participate in the study. As reflected in our staged consent process, all patients seeking care from any MSHC practice site may upload the mHealth Suite at any time without consenting to participate in any other aspects of the study. All other participants will self-initiate their

participation by interacting at will with the mHealth Suite and by contacting the study staff at their own will. They will be informed on all consent forms and during the consent process that they will be able to decline to participate in any element of the study or withdraw from the study completely at any time. Participants may delete the apps that they uploaded onto their smartphones at any time. Additionally, there will not be a monetary award or any reimbursement for participating in the study or any other information given to subjects that do participate in the study that other subjects would not have access to.

Clinical procedures and responsibilities are within standard scope of practice for diagnosing and treating COVID-19. These standards of practice will not deviate for research purposes.

## **6.0 Study Design and Procedures**

**Collaborating Sites:** The University of Chicago Hospital, UI Hospital, the UIC School of Public Health, and the UIC College of Applied Health Sciences, in collaboration with FQHC-MSHC main and its 13 other practice sites, already possess the necessary leadership support, staff, and institutional-organizational infrastructure to facilitate COVID-19 self-testing uptake. There will be no other collaborators, outside of business owners, religious leaders, and leaders of community-based organizations who are willing to disseminate or post study ads. As part of usual care, the MSHC practice sites will provide preventative and follow-up outreach to our communities and transfer all data to public health officials. As a clinical-community psychologist specializing in community-based epidemiological and biobehavioral-health-science research in Chicago's underserved neighborhoods for over two decades, PI Ismail brings a unique interdisciplinary perspective to cross-site-collaborative project design, implementation and oversight. Co-I Jasenoff, Chief Medical Officer of the FQHC-MSHCs brings coordination and leadership to the staff necessary to seamlessly execute the NIH-RADx-UP project. Co-I Basu, the director of the Center of Biostatic Development, has headed efforts with the City of Chicago to analyze COVID-19 data to facilitate informed public health decisions. PI Ismail directs the Clinical Microbiology lab at UIC and is a leader and well-respected innovator in the area of infectious diseases diagnostics, including COVID-19. Allen McLean and Matthew Trunnell will serve as consultants and are all internationally recognized for their research and implementation of persuasive and accessible mHealth technologies related to the creation of our COVID-19 mHealth Suite.

### **Study Design and Procedures: Study Design**

#### **Diagnostic Testing Component**

We will apply a pre-post-test, repeated-measures, mediational design to test whether our mHealth COVID-19 Literacy and Outreach Suite and person-centered testing choices (self-collection versus on-site point of care) approaches will lead to higher rates of COVID-19 testing uptake compared with baseline rates. Seven thousand symptomatic and asymptomatic child and adult participants will be consented and enrolled to undergo diagnostic testing for COVID-19 on site or at home (with detailed instructions contained in the self-testing kit) via nasal nares swab at one time point over a 28-day period. Time 0 nasal swabs collection will be defined as the first time a participant chooses to undergo COVID-19 testing.

#### mHealth Educational/Outreach Component

At or before Time 0, participants will also be invited to utilize a suite of COVID-19-related smartphone apps and videos, referred to as the COVID-19 mHealth Literacy and Outreach Suite. These smartphone apps and videos will be co-created as part of this grant, with advice from healthcare providers and members of a community advisory board at the Mile Square Health Center. Two of the apps that are to be included in this Suite already exist as follows: (1) The COVID-19 Stoplight App is a self-report measure of COVID-19 symptoms. Participants will be able to access and utilize this app to report any symptoms that they have that may be suggestive of COVID-19. A link to a working version of this app may be found here: <https://covidstoplight.org/> and (2) COVID Coach Mental Health symptom reporting and psychoeducational coping app, published by the Veterans Administration: [https://www.ptsd.va.gov/appvid/mobile/COVID\\_coach\\_app.asp](https://www.ptsd.va.gov/appvid/mobile/COVID_coach_app.asp). Among the other apps will include (3) a to-be-constructed Enrollment App, where participants will be able to provide consent for sharing the de-identified data they provide when responding to questions in the apps with UIC, the National Pandemic Commons, the Chicago Department of Public Health, the Cook County Department of Public Health, and the Illinois Department of Public Health. We will also include (4) a COVID-19 Test app that would enable participants to view instructions on how to self-collect their nasal swab sample, collect a sample from their child, and locate one of the 14 Mile Square Health Center practice site drop-off points to deposit their sample, or, phone for the study courier to pick up the sample to deliver it to the lab. The Group Settings app (6) will prompt participants to identify public settings where large groups of people are congregating without wearing masks or practicing physical distancing (by entering the name and address of the public setting). The mHealth Suite will also include three brief educational videos, to be made in collaboration with staff and volunteers from the Mile Square Health Center practice sites. One will focus on providing clear, consistent, basic information about COVID-19, one will focus on things people can do to prevent infection and spread of COVID-19, and one will focus on self-care tips and how to utilize at-home medical devices should a person become diagnosed with COVID-19.

#### Telephone Interview Component

The student research assistants will interview all participants by telephone at Time 0. Information to be collected by phone at Time 0 will include participants' age, race, ethnicity, current sex, sex-at-birth (if different), employment status, and educational attainment. Information to be collected from all participants (including the 300 community champions) by phone at Time 0 will include the COVID-19 knowledge questionnaire and COVID-19 knowledge, social capital, racial/ethnic stigma, risk & preventative behaviors (Sub aim 1.1). On Day 28, for test-positive subjects only (Sub aim 1.2) we will also measure, time-to-diagnosis, healthcare seeking, COVID-19 disclosure, medical adherence, home self-isolation and public self-quarantine, and other infection control parameters and we will also assess the impact of testing positive using the PhenX Impact of COVID-19 on Behavior: Stress, Anxiety, Food or Economic Insecurity, and Mental Health measure. (Please refer to the specific item questions for all of these variables later in this document and also contained in the file, entitled, COVID-19 Testing Choices Assessment).



While all participants, children and adults, will participate in the nasal swab collection for COVID-19 diagnostic testing, only those ages 18 and above will be enrolled in the smartphone apps assessment, telephone interview assessment portions of the study. This is due to the fact that the assessments being used have not been validated in samples of children.

These different approaches to recruitment and enrollment will allow for testing and enrollment of symptomatic and asymptomatic individuals, to be analyzed with different probabilities of testing positive, who are diagnosed to be either test-positive or negative. Procedures to obtain COVID-19 testing (for adults able to come on-site) for this study will be made available free of charge, with no proof of insurance required, from the 14 participating Mile Square federally qualified health center practice sites (FQHCs). Irrespective of the initial COVID-19 test outcomes, all enrolled participants will be invited to: (a) use the mHealth COVID-19 Literacy and Outreach Suite at their own will, and (c) undergo a 10-15 minute, baseline phone interview and three additional, 15-minute phone interviews during the same 28-day period (checking on status, recording social-demographic information, and assessing our behavioral health mediators of COVID-19 knowledge acquisition COVID-19 knowledge, social capital, racial/ethnic stigma, risk & preventative behaviors ([refer to COVID-19 Testing Choices Assessment](#))).

Testing of nasal swabs will be treated as conventional care for patients of the 13 Mile Square Health Center practice sites. Additionally, the mHealth COVID-19 Literacy and Outreach Suite will be made available to all patients at the 13 Mile Square practice sites. Each participant will receive nasal swabs testing one time during a 28 day period that begins with their first nasal swab-based test. Blood testing and the telephone interviews will be considered experimental and not part of conventional care.

At any time during the study, participants with COVID-19 symptoms who are in need of telehealth or in-person care for symptoms or complications of COVID-19, or any other medical or psychiatric condition, may be advised by study personnel to access their nearest MSHC practice site (or nearest Emergency room, when indicated). Any treatment received will be considered usual/standard care treatment and will not be included as a part of this research study. There will be no other unscheduled visits in this study.

The COVID-19 nasal swab testing being administered to participants in this study may also be considered standard care medical procedures, particularly for subjects reporting COVID-19 symptoms or an exposure to someone with COVID-19. However, enrollment in each smartphone App is solely being done for research purposes. Figure 1 (shown earlier on page 7 of this protocol) presents the study participant and enrollment process and Figure 2 presents a prototype of the to-be-developed mHealth suite of apps and videos.

## COVID-19 mHealth Literacy & Outreach Suite

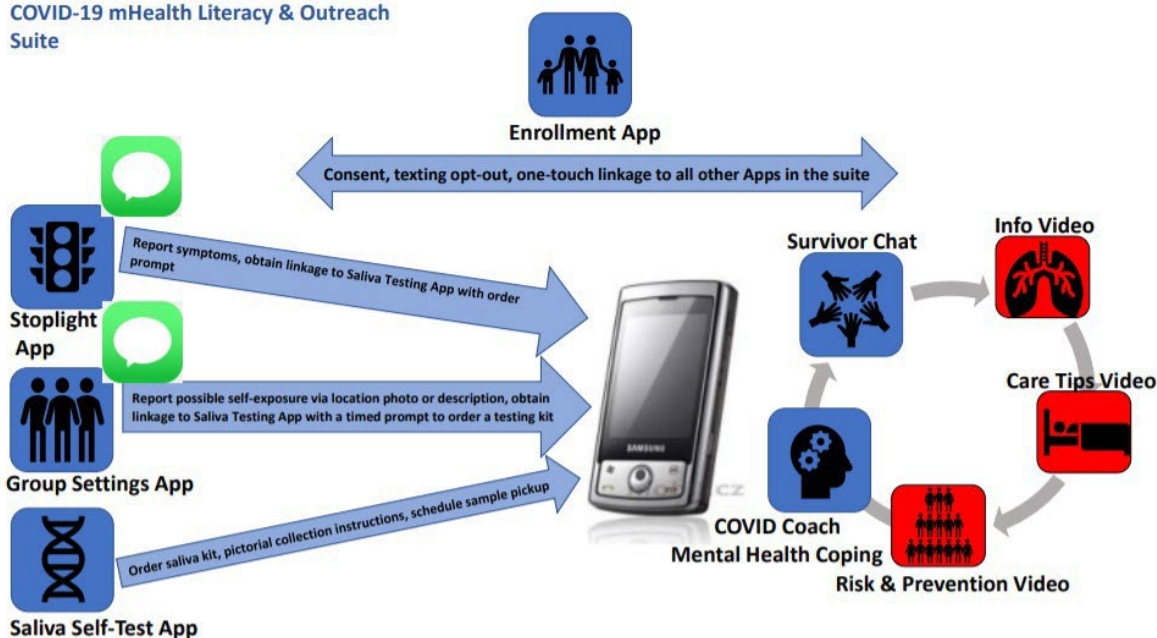


Figure 2: mHealth Literacy and Outreach Suite

## Specimen Collection Studies

Procedures to obtain COVID-19 testing (for adults able to come on-site) for this study will be seamlessly integrated into the existing on-site and/or telehealth operations of the MSHC practice sites.

**Nasal Nares Swab Collection (Remote and On-site):** CDC guidelines will be followed in the collection of nasal nares samples <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>. An individually-wrapped, flocked or spun polyester sterile swab for upper respiratory specimen collection will be used. Swabs will be placed immediately into a sterile transport tube containing 2-3mL of viral transport medium (VTM). Subjects will be invited to provide one nasal swab specimens throughout the 28-day course of their study participation.. Subjects may elect to self-collect their nasal swab remotely or provide a sample on-site at one of the 14 MSHC practice sites (Monday – Sunday, with days and times open varying per site). All on-site collections will take place by appointment with the research staff in a designated exam room within each of the 14 MSHC practice sites. According to the requirements of the Illinois Departments of Public Health, the collection vials will be labeled in advance with the subject's name, telephone number, date of birth, and (meaningless) study ID number. MSHC staff collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2 will be instructed to maintain [proper infection control](#) and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

Healthcare and laboratory personnel who are handling specimens, but are not directly involved in collection (e.g. self-collection) and not working within 6 feet of the patient, will follow [Standard](#)

Precautions. Healthcare personnel are recommended to wear a form of source control (face mask), eye protection, and gloves at all times while in the healthcare facility or lab. All persons will be instructed to only grasp the swab by the distal end, using gloved hands only. Participants collecting remotely will be provided with the following instructions in the kit and via the mobile web app.

### **General Nasal Swab Collection Instructions**

- 1) Please plan to collect your nasal swab sample on the same day that you plan to drop it off at the clinic drop-off site or call for the study courier. **Samples not collected on the same day that they are dropped off will not be viable.** View the list of UI Health clinics and corresponding pick-up hours enclosed in your box. Select a site where you or someone in your household will be able to drop off your nasal swab sample, once it is collected.
- 2) Be sure to allow enough time for you to collect and deliver your sample before the last pick-up time listed on the enclosed schedule. If you have any questions, please telephone the UI Health clinic where you plan to drop off your sample. **The center must be open in order for you to be able to drop off your sample.**
- 4) Wash your hands with soap and warm water for at least 20 seconds or utilize a hand sanitizer with at least 60-90% alcohol, before beginning.
- 5) Open the kit containing the individually-wrapped nasal swab, instructions and consent form.
- 6) Please read and sign the consent form, answering the questions at the bottom of the consent form to verify your understanding of study procedures.
- 7) Set the enclosed plastic bag aside. Place it in a pre-sanitized, separate area on a table, desk, or counter. This is where the sample vial will eventually be placed after collection.
- 8) Place the vial that is provided on a table in front of you.
- 9) Open the nasal swab wrapper at the end that does not have the absorbent tip and grasp the flat/hard end of the swab.
- 10) Using the swab, insert the entire absorbent tip of the swab (usually  $\frac{1}{2}$  to  $\frac{3}{4}$  of an inch (1 to 1.5 cm) inside the first nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. Using the same swab, repeat in the other nostril, rotating the swab against the nasal wall at least 4 times. Take approximately 15 seconds to collect the sample from each nostril. Be sure to collect any nasal drainage that may be present on the swab.
- 11) Break open the top of the vial and place the absorbent tip of the swab with your sample on it all the way into the vial until it hits the bottom of the vial. Rotate the tip of the swab so that it may be washed in the liquid that was already present in the vial.
- 11) Re-wash your hands with soap and warm water for at least 20 seconds or utilize a hand sanitizer with at least 60-90% alcohol.

- 12) Place the collection vial containing your sample in the plastic specimen bag that you set aside before sample collection. Please make sure the bag is completely sealed.
- 13) Place the specimen bag back into the original kit that it came in. **Fold and include the signed consent form in the same kit.** Keep the unsigned copy of the consent form for your own records. **Samples will not be processed unless the consent form is returned.** Re-seal the kit using the CONFIDENTIAL and BIOHAZARD DO NOT OPEN stickers provided, leaving the “return to” address of the UIC Clinical Microbiology Lab in clear view.
- 14) Drop your sample off or call for courier pick-up **on the same day that it is collected** at one of the listed clinics that is most convenient for you. Be sure the clinic will be open before you arrive and check in with the front desk staff or security guard to provide your box containing the consent form and swabs sample. No payment or proof of insurance will be requested or necessary in order to have your sample processed and analyzed.
- 15) If there is a delay in dropping off your sample or in courier pick-up, store the sample in your refrigerator at 37 - 46°F for up to 72 hours after collection. When it is time to deliver the sample to the laboratory, break open the ice pack that is included with your kit and send or deliver your sample on ice.

## HOW TO COLLECT YOUR ANTERIOR NASAL SWAB SAMPLE FOR COVID-19 TESTING



Follow the instructions included with your sample kit. Use **only** materials provided in your kit to collect and store your sample, unless the kit says to do otherwise. Use **only** an approved sampling kit given to you by your healthcare provider or by personnel at the testing center.

### Initial set-up

1. Open the sampling kit.



2. Apply hand sanitizer with at least 60% alcohol.

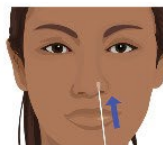


### Sample collection

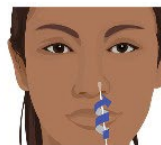
3. Remove the swab from the container, being careful not to touch the soft end with your hand.



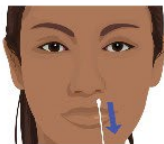
4. Insert the swab into your nostril. Do not insert it more than half an inch into your nostril.



5. Slowly twist the swab, rubbing it along the insides of your nostril for 15 seconds.



6. Gently remove the swab.



7. Using the same swab, repeat steps 4-6 in your other nostril.



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

### Preparation of sample for return

8. Place the swab in the sterile tube and snap off the end of the swab at the break line. Place the cap on the tube.



9. Re-apply hand sanitizer.



10. Place the tube containing the swab in the biohazard bag provided and seal the bag.



### Returning the sample and clean-up

11. Give the bag with the swab to testing personnel.



12. Throw away remaining sample kit items.



13. Re-apply hand sanitizer.



Because we are testing each of 7000 participants four times, we anticipate collecting a total of 28,000 nasal swab samples during the study performance period. This equates to approximately 90 samples per day, with approximately six-to-ten samples being collected from each site, per day. Based on the validation studies, the samples are stable at room temperature (25-30°C) for up to 24hrs or, if they are refrigerated, they are stable for up to 72hrs. Thus, stability of the samples will be ensured by instructing patients to self-collect their samples on the same day that they are to be dropped off at the practice site. Once dropped off at the front desk of the clinic, the healthcare provider receiving the sample will place it into a disposable (corrugated box) multi-sample organization and shipping container clearly marked "COVID-19 Testing Choices" Biohazard – Authorized Personnel Access Only" for pickup by the study courier. If samples are dropped off following the last courier pick-up time, they will be stored until the next pick-up day in an on-site locked study mini-refrigerator clearly marked "COVID-19 Testing Choices" Biohazard – Authorized Personnel Access Only" and transported to the lab during the next available courier route.

Testing access and uptake will be facilitated by timely/scheduled sample pick-up of samples by a medical courier company and/or trained assistant from the laboratories of Dr. Ismail or Ismail. All individuals handling samples will be trained in institutional biosafety and will take the online Coursera course on COVID-19 for health care providers via Stanford University: <https://www.coursera.org/learn/covid-19-training-healthcare> as well as the UIC Institutional Biosafety Course and COVID-19 campus safety training. Appropriate PPE for any UIC assistant will be provided by the Ismail or Ismail lab and will include an N95 mask, face shield and scrubs. Sample pickups will occur from the 14 Chicago-area FQHC sites and drop off to the centralized Clinical Microbiology Lab at UIC (Dr. Ismail Lab). Please refer to the Courier Transport Schedule, below. We selected the following drop-off and pick up approach for several reasons: 1) These cutoff times will enable the lab to process up to ~3000-6000 tests per day with a 24hr turnaround time (which is a much larger amount than expected); 2) this will ensure patient

privacy, adequate data entry and documentation of consent, minimal physical contact with the courier, and reduction of the courier's workload, travel time, and expense.

Similarly, all nasal swab samples collected on-site at one of the 14 participating practice sites will be placed into a disposable (corrugated box) multi-sample organization and shipping container for pickup by the study courier. A similar, secure sample drop-box will be available at the front desk of every MSHC practice site for the healthcare staff to deposit subject samples for courier pick-up. The shipping containers will be picked up at all 14 sites according to the following courier pick-up schedule by the study courier and transported directly to Dr. Ismail's clinical microbiology lab.

#### **Courier Transport Schedule: MSHC practice sites to Ismail Lab**

<b>MSHC Practice Site</b>	<b>Mon Pick up times</b>	<b>Tues Pick up times</b>	<b>Wed Pick up times</b>	<b>Thurs Pick up times</b>	<b>Fri Pick up times</b>	<b>Sat Pick up times</b>	<b>Sun Pick up times</b>
UI Health Acute Care	9:30, 5:00	9:30, 5:00	9:30, 5:00	9:30, 5:00	9:30, 5:00	12:00 5:00	12:00 5:00
Mile Sq Main	10:00, 4:45	10:00, 4:45	10:00, 4:45	10:00, 4:45	10:00, 4:45	11:45	Closed
National Teachers	10:30	10:30	10:30	10:30	10:30	Closed	Closed
Hope Institute	9:00	9:00	9:00	5:15	9:00	Closed	Closed
Bronzeville Calumet	10:45	10:45	10:45	10:45	10:45	Closed	Closed
Barnes-Boyd	11:00	11:00	11:00	11:00	11:00	Closed	Closed
Humboldt Park	8:30	8:30	8:30	8:30	8:30	Closed	Closed
Back of the Yards	1:00	1:00	1:00	1:00	1:00	11:00	Closed
Cicero	2:00	2:00	2:00	2:00	2:00	Closed	Closed
Davis	1:30	1:30	1:30	1:30	1:30	Closed	Closed
Englewood on 63rd	4:00	4:00	4:00	4:00	4:00	Closed	Closed
Englewood on Normal	3:45	3:45	3:45	3:45	3:45	Closed	Closed
South Shore	3:15	3:15	3:15	3:15	3:15	10:00	Closed

#### **Storage, Retention, and Labeling of Nasal Swab Specimens**

Following processing, diagnostic testing, and antibody testing described in this proposal, all stored specimens retained at UIC will be kept in a locked freezer in Co-I Nahed Ismail's Clinical Microbiology lab until study termination. As required by the Illinois Departments of Public Health, the samples will be labeled with each subject's name, date of birth and telephone number marked on the label on the outside of the tube or vial. All biospecimen and COVID-19 symptoms



results data from the COVID-19 diagnostic testing will be shared according to data sharing agreements with the National Pandemic Commons (COVID-19 symptoms data from the STOPLIGHT symptoms app) and the Illinois Department of Public Health. While the results data shared with the National Pandemic Commons will be de-identified, the results shared with the Illinois Department of Public Health require by law that subjects' identifying information be provided along with the COVID-19 testing results, so all results shared with these entities will be identifiable by subject name, date of birth, and telephone number, and home address. Other information about the subject will be entered into the Illinois Department of Public Health REDCap portal, here <https://redcap.dph.illinois.gov/surveys/?s=FR7MAJAY84> In addition to the authorized State, City, and County Public Health Officials, access to these samples will be given only to the PIs Al-Hendy, Ismail and Ismail. Subject specimen collection vials will be pre-labeled before distributing to participants. Dr. Nahed Ismail will be responsible for keeping the samples safe and for keeping the analytical data secure through the REDCap database. All other data generated by the mHealth Suite, the contact tracing, and by the telephone interviews and all results generated via diagnostic testing and related analyses, will be securely collected according to all standards of care and stored for at least two years following termination of the study in the REDCap database.

### **Testing of Nasal swabs**

1. Self-collected Nasal swabs collected under clinical supervision, in the clinics, will be tested by the Abbott RealTime SARS-CoV-2 assay and using the Abbott m2000 platform. The test is a reverse transcriptase real time PCR (RT-PCR) that detect the SARS-COV2 RNA (nucleic acids) in human samples. The test is approved by the FDA under EUA. The test will be performed at the CLIA-certified Clinical Microbiology Laboratory at UIC.
2. Self-Collected nasal swabs at home (without clinical supervision) will be tested by the Sofia SARS Antigen Fluorescent Immunoassay (FIA). The assay is an FDA approved under EUA. The assay uses advanced immunofluorescence-based lateral flow technology in a sandwich design for qualitative detection of nucleocapsid protein from SARS-CoV-2. The Sofia SARS Antigen FIA, with the Sofia 2 and Sofia analyzers, provides automated and objective results in 15 minutes, allowing for testing of patients suspected of COVID-19/2019-nCoV in near-patient testing environments. However, all testing will be done at the CLIA-certified Clinical Microbiology Laboratory at UIC.
3. Self-Collected nasal swabs at home (without clinical supervision) will be also tested by ELLUME test. The ellume test is a hand-held, versatile digital device that will be used as point-of-care test (POCT). This fully at-home diagnostic test for COVID-19 is a rapid, lateral flow antigen test, a type of test that runs a liquid sample along a surface with reactive molecules. The test detects fragments of proteins of the SARS-CoV-2 virus from a nasal swab sample from any individual, all age groups, with suspected SARS-COV2 infection.

### **Destruction of Specimens**

All specimen samples will be destroyed immediately after the publication period or within a two-year period, whichever comes first. The samples will be placed in a secure biohazard container and picked up by a medical waste hauling company based on the standard practices within the UI Health protocol.

### **Telephone Interviews, mHealth Suite Data Extraction, and Contact Tracing Interviews**

#### ***Telephone Interviews***

As described earlier in this protocol, all participants will undergo a 40-60 minute, baseline phone interview on Day 1 and one additional, 40-60-minute phone interview on Day 28 after testing. During these interviews, which are contained with scripts in the Appendix under NIH RADx-UP Survey and consent Questionnaire, a research assistant will be assessing COVID-19 symptoms (for both children and adults), recording social-demographic information (for both children and adults), and assessing the COVID-19 determinants of health described previously and contained in the COVID-19 Testing Choices Assessment (for adults only). Subject identifiers and social-demographic data be stored separately from the other data in a different REDCap database on a different server and will be saved for a period of 2 years. The self-report data will be linked to the identifiers via a meaningless numeric subject ID code. The COVID-19 social determinates questions will include questions about contagion, spread, symptoms, and prevention (30). COVID is an emerging area; therefore, validity and reliability data are not abundantly available. Due to the urgency of executing this study in this rapidly evolving pandemic, we will not have the opportunity to pilot the questionnaire before recruiting participants. All assessment questions are derived from the NIH PHENx item/assessment bank, as per the requirements of this funding announcement. All self-report questions will be administered in English and in Spanish. All data will be recorded into a REDCap database and stored in a secure server in Co-I Basu's lab.

### ***mHealth Data Collection and Extraction***

Ongoing data throughout each participants' participation will be extracted from subjects' responses to questions contained in the symptoms reporting app, the Group Settings App, and the Nasal Swab Test Ordering App (all to be developed during the study) as follows.

Enrollment app: This app will only collect the subject's telephone number and no other identifying information. It will provide the screening questions described in the preceding section, and, if the screening questions are answered 'yes,' this app will also provide a digital consent form that will only cover consent for data collection from the symptoms reporting app, the group settings app, the nasal swab-based test ordering app and the survivor chat app. Data extracted from these apps will be extracted into the CCTS REDCAP.

Symptom Reporting (STOPLIGHT) app: the symptom reporting app assesses symptoms of COVID-19 via subject self-report. Data extracted from this app will be extracted into the CCTS REDCAP.

Group Settings app: the congregate settings app will allow for participants to identify a congregate setting by typing a description of it and address into the app. Participants will be prompted by a text that reminds them to report this information whenever they notice a crowded setting where people are not wearing masks or practicing physical distancing. Data extracted from this app will be extracted into the CCTS REDCAP.

Nasal Swab Test Ordering app: Subjects will enter their names, phone number and address of residence so that they may receive the nasal swab test ordering kit by courier. The kit will contain the consent form for the nasal swab collection and telephone interview aspects of the study. Data extracted from this app will be extracted into the CCTS REDCAP. Any identifying information, due to HIPAA, will be collected independently of App usage via phone.



## **Contact Tracing Interviews and Resulting Data**

The initial contact tracing call with a subject who tests-positive for COVID-19 will include:

1. Positive result notification
2. Current Symptom Checklist (the same symptoms that are contained in Question 1 of the COVID-19 Testing Choices Questionnaire)
3. An elicitation of contacts and possible sources of exposure. This will involve interviewing the subject who has tested positive for the disease (the “index patient”) to create a list of adults and children with whom the index patient was in close contact (within 6 feet) for more than 15 minutes, starting from 48 hours before illness onset. CDC’s CovidTracer 1.0 spreadsheet-based tool provides 5 – 20 as an illustrative range for contacts per case whereas estimates of the basic and effective reproduction numbers (expected number of infections from one case)  $R_0$ , and  $R_e$  vary between 2.0 to 5.7 in the literature.
4. A resource check where we will re-administer questions 10 & 11 from the Adult Baseline and 9 & 10 from the Child Baseline COVID-19 Testing Choices Questionnaire, contained in the Appendix.
5. Establishing isolation, which will involve making a customized plan with each participant reviewing the details of their living space and discussing options for how they plan to self-isolate from others within their household, to the extent possible.
6. Setting the expectation of a daily check-in via a text reminder to report daily symptoms using the COVID-19 symptom reporting stoplight app for a period of the next 14 days, with the recommendation that they do not hesitate to call their healthcare provider, a MSHC practice site (312) 996-2000, or 911 in an emergency, if any symptoms should emerge.

We will recommend that individuals engage their providers for any symptoms they experience, and if they’re a contact we will refer them to their primary care provider or offer them the opportunity for testing through participation in the nasal swab testing aspect of our study (and in any other aspects of our study in which they choose to participate). Prospective participants identified through contact tracing of test-positive subjects will be invited to participate in the study using the Recruitment Flyer referred to previously in this protocol. We will also reiterate on every call with a test-positive participant the emergency warning signs for COVID (highlighted in our list of symptoms in the Question 1 of the COVID-19 Testing Choices Questionnaire) and remind people that if they experience these symptoms then they need to seek emergency help immediately. Consistent with study aims, we will also encourage participants to engage with the apps and videos in the COVID-19 mHealth Literacy and Outreach Suite to increase their knowledge and self-care agency during their convalescence. As part of the contact tracing process, there will be restrictions on how many attempts we make when attempting to reach people who do not respond to our calls. After seven failed attempts, we will seek assistance with establishing contact with the subject’s contacts from the Illinois Department of Public Health.

By Illinois Law, the contact tracing data that will be collected using CCTS REDCap will contain participants' names, addresses, dates of birth, and telephone numbers. These REDCap data will be stored in a secure server within Co-I Basu’s lab and also reported to the Chicago Department of Public Health via their secure REDCap data reporting:

<https://redcap.dph.illinois.gov/surveys/?s=FR7MAJAY84>. By mandate of the funder, contract tracing and self-report data will be shared with the Illinois Departments of public health through

a secure, encrypted REDCap portal <https://redcap.dph.illinois.gov/surveys/?s=FR7MAJAY84> to which they will be given access. If the system that they are currently using, Sales Force, becomes available, we will write an amendment to this IRB to change from REDCap to Sales Force.

All other self-report data collected via telephone interview and the Smartphone apps described in #2 will be collected via the secure CCTS REDCap and coded with a meaningless numeric subject ID code that will be linked to a separate list containing each subject's name, phone number, email address and street address of residence. This contact list will be stored separately in a different password protected folder on an entirely different secure server (in the laboratory of PI Nahed Ismail) than the deidentified raw self-report REDCAP data, which will be stored on a server in the laboratory of Co-I Basu.

## **7.0 Expected Risks/Benefits**

### ***Risks***

The primary risk of participating in this research study is the possibility of a PHI data breach or a breach in confidentiality. Additionally, there is the possibility of false-positive (rare) or false-negative COVID-19 testing results, which may have implications for potential unintentional transmission of the disease. This research has several other risks. Social, legal, economic, and psychological risks include the threat of loss of confidentiality of protected health information, particularly if a subject tests positive for COVID-19. Furthermore, a positive COVID-19 result or other associated abnormality/complication, if accidentally disclosed, may result in social stigmatization, and threats to employability, insurability, and social status in the event of breach of confidentiality regarding a positive result. Other psychological risks include the fact that some subjects may worry about heritability of a suspected COVID-19 risk factor or spread of the COVID-19 to their born or unborn children.

The risks of false-negative or rare false-positive results will be mitigated by our study design. The risks for a PHI data breach will be mitigated by strict adherence by study staff to the use of the CCTS REDCap portal and data management/storage system. Risks to the loss of confidentiality of the self-report data will be mitigated through the indirect coding of these data using a meaningless numeric subject ID code, which will be linked to the subject's identifying information and consent forms that will be stored separately in a separate server and (for paper forms) in a locked cabinet in the PI Ismail's lab room (AHSB 322). Risks to the loss of confidentiality of the data extracted from the mHealth apps will be mitigated by having the subject only report a telephone number on the Enrollment App and no other information. Additionally, all apps will be encrypted and data resulting from these apps will be downloaded into a secure CCTS REDCap database. Risks to the loss of confidentiality of all other self-reported study interview data will be mitigated by having a pre-assigned, meaningless numeric study ID code serve as the indirect identifier and by storage in the CCTS REDCap database. Risks to the loss of confidentiality of the contact tracing interview data will be mitigated by entry and storage in the CCTS REDCap database. Risks to the loss of confidentiality during sample transport will be mitigated by having each subject apply the stickers that say "CONFIDENTIAL" and "BIOHAZARD: DO NOT OPEN" on the box for each nasal swab kit following sample collection, along with instructions to return the box to the PI, Ismail's, lab at UIC if a lost sample is found.

### ***Benefits***

Being in this research study will not benefit the participants directly. However, our provision of clear, scientifically-informed healthcare information regarding COVID-19 via the mHealth Literacy and Outreach Suite of apps and videos may increase knowledge, self-care agency, and communication with the study community, possibly leading to the likelihood that subjects will be more likely to reach out for care, when needed. Moreover, the delivery of timely COVID-19 diagnostic testing results, antibody results, and early linkage to healthcare may lead to earlier healthcare seeking, which, in some cases, could attenuate complications and/or prevent deaths. There are no other anticipated benefits to participation.

## **8.0 Data Collection and Management Procedures**

All data generated by the mHealth Suite and by the telephone interviews, all nasal swab specimens, and all results generated via diagnostic testing and related analyses, will be securely collected according to all standards of care. Any identifying information, per HIPAA, will be collected independently of the mHealth Suite via phone interview. Data will be analyzed and shared with the Illinois Department of Public Health following all applicable laws and regulations. Sharing will occur as data are generated and via CCTS REDCap. Data from the study will be securely stored through encryption, password protection and the use of Redcap. Data from the apps in this study will only contain de-identified information and will be extracted directly from the apps into a secure, encrypted REDCap server. All other self-report data will be collected via telephone and will be entered directly into a REDCap Database. The sharing of all data with the Illinois Department of Public Health will be endorsed on a UIC data sharing agreement form. Our informed consent and IRB approval processes will include the provision that all data and specimens will also be made available for sharing and/or testing within our laboratory.

All biological specimens will be retained in a designated, locked, study freezer within the lab of PI Dr. Nahed Ismail, who will be responsible for all biological specimens and resulting results/data, which will be entered into a secure, encrypted, CCTS REDCap database.

All other self-report data resulting from the (1) telephone interviews (indirect identifiers), contact tracing interviews (direct identifiers), and data extracted from the mHealth apps (phone number only) will be entered into three separate secure encrypted CCTS REDCap databases, respectively. Each database will be stored in Co-I Sanjib Basu's lab within the School of Public Health.

## **9.0 Data Analysis**

All data analyses will be conducted under the supervision of Co-I Sanjib Basu within his laboratory (Center for Biostatistical Development) in the School of Public Health. With respect to data endpoints and statistical analysis, as part of an already completed Data Use Agreement between UIC's School of Public Health and the City of Chicago, we will utilize individual-level test-positive case data from the City of Chicago as a comparator reference baseline to assess the proposed outcomes. For Sub-aim 1.1, *Estimate the baseline rates of testing uptake, COVID-19 positivity rate, and deaths in the 14 FQHC catchment areas, examining PhenX barriers and facilitators as mediators*, we will use an existing Data Use Agreement with the City of Chicago. Co-I Basu will access individual-level test-positive case data to use as a comparator reference to estimate the average historical baseline testing uptake in the 14 areas. We will consider swab test-positive as a binary (yes/no) subject-level endpoint. Proportion of test positives within each sub-aim cohort will be compared with the appropriate City of Chicago reference data with the caveat that sub-aim 1.1 and potentially 1.2 cohorts are higher-risk because they are already seeking care.

We will also consider multivariable regression analysis adjusted by demographics (gender, age, ethnicity) and the PhenX testing barrier and facilitator mediator variables as well as assess time-trends in test positivity in the study cohort with Chicago Department of Public Health-reported trends. Specific PhenX mediators collected on the 28th day after initial testing will include: COVID-19 knowledge (PhenX COVID-19 knowledge, attitudes, and behaviors items 19-31), COVID-19 social capital (items 12-16, PhenX Toolkit COVID-19 Community Response Survey), racial/ethnic stigma (PhenX Coronavirus Racial Bias Scale), and COVID-19 risk & preventative behaviors (items 15-18 from PhenX Toolkit COVID-19 Knowledge, Attitudes, and Avoidant Behaviors).

In secondary analyses, we will further disaggregate the sample of those tested according to collection & results-delivery choice in a comparative-effectiveness analysis of willingness to retest (proportion of frequency counts per number of retest recommendations) and testing satisfaction (questionnaire to be developed). Data from the sequence of repeated tests for the same subject will be analyzed using longitudinal statistical analysis approaches. We further propose to assess adoption of Aim 1 with the Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM), which together comprise 8 questions, each on a 5-point Likert scale. Our symptomatic sentinel surveillance cohort is higher-risk (as they are already seeking care), but testing uptake in the other cohorts are expected to reduce the test positivity rate. Our study is expected to have approximately 80% power to detect a 1% change in positivity rate at 0.05 significance level. Based on our past experience with large-scale epidemiological studies (30), we will conservatively anticipate an attrition rate of 25% over the 28-day period where repeated collections will be requested. This effective sample size of 5,250 will offer more than 80% power to detect even a small effect size measured by  $f^2=0.004$  or larger for the multivariate (regression) analyses planned herein.

For Sub-aim 1. 2, *In the ~671 test-positive participants (~503 considering 25% attrition), we will test all individuals ;symptomatic and asymptomatic , only one time.* These data will be correlated (in related studies by our team at UIC) with clinical history, seroprevalence data in both asymptomatic and symptomatic populations, and with serum IgG titer, as well as level of neutralizing antibodies as markers of protective immunity against COVID-19.

These data will provide key information for future evaluation of potential vaccine or novel therapeutics against COVID-19. In test-positives, we will also administer PhenX social-determinants measures on the 28th day following initial testing to assess the effects of the testing and mHealth intervention on retesting uptake (proportion of frequency counts per number of retest recommendations), time-to-diagnosis (days from date of symptom onset or exposure), health care seeking (items 2-13, PhenX Toolkit COVID-19 Symptoms, Status, and Healthcare), COVID-19 disclosure (items 11 & 12, PhenX Toolkit COVID-19 Symptoms, Status, and Healthcare), medical adherence (items B6-B14 from PhenX Coronavirus Testing and Treatment MICS-WIHS), and practice of home self-isolation, public quarantine, and other infection control behaviors (PhenX Social Distancing and Restricted Activities Perinatal Experiences Study + items 16-18 from PhenX Toolkit COVID-19 Knowledge, Attitudes, and Avoidant Behaviors). We will also assess the economic and psychosocial consequences of testing positive using the PhenX Impact of COVID-19 on Behavior: Stress, Anxiety, Food or Economic Insecurity, and Mental Health measure.

An effective sample size of 503 will provide 80% power to detect an individual small effect size of 0.125 or larger or a correlation of 0.125 or larger at a 0.05 significance level. The outcomes

will be summarized descriptively and analyzed using appropriate regression and other multivariable models. Viral load and other repeated measures will be analyzed using longitudinal models and will be associated with both clinical outcomes as well as demographics and various PhenX (social determinants and other) measures.

For Sub-aim 2.1-2.2, *expand community-based testing via engagement of 300 community champions and testing collaboration with high-risk settings*, we will apply participatory methods to analyze the social, ethical, economic, and behavioral drivers and consequences (barriers and facilitators) of our outreach and testing approaches. We will compare the 300 champions with the other 7,000 participants to assess the effects of participatory action on PhenX-defined COVID-19 knowledge and PhenX-defined COVID-19 social capital. Based on advances in empowerment theory (31) we hypothesize that COVID-19 knowledge and social capital will increase as a result of co-creating and disseminating study ads, locating high-risk congregate settings for testing kit distribution, and co-constructing the mHealth Literacy and Outreach Suite. Assuming 25% attrition, these sample sizes will provide 80% power to detect even small differences at an effect size of 0.2 or larger at the 0.05 level. These outcomes will be compared using univariable and multivariable approaches appropriate for binary, ordinal and other outcomes.

## **10.0 Quality Control and Quality Assurance**

The PI, Nahed Ismail will ensure project delivery by coordinating all interprofessional, community, and patient-level mHealth and outreach programming and research, along with preparing necessary data/specimen sharing, and coordinating progress reports. PI Ismail will conduct all microbiological testing, interpretation, analysis and data transfers. Co-I Basu will oversee data security, data compliance, data transmission, data storage and data analysis, in collaboration with PI's Ismail, Ismail, the project manager, and the mHealth collaborators (Trunnell, Neuner, and McLean). These mHealth collaborators will oversee app development and testing and will advise on secure and compliant technology solutions for linkage between the different mobile technologies and the HIPPA-compliant web-based platform and server. A Research Technologist for Dr. Ismail will oversee all biospecimen transport to and from the lab to the 14 MSHC practice sites and will assist with laboratory testing. FQHC Co-I Jasenof will guide the project team in the integration of project related services into the FQHC clinical care workflow. A Research Coordinator (To be Named) will facilitate recruitment and will conduct all project-related formative evaluations and outcomes interviews and a Patient Disease Navigator (To be Named), will inform patients of test results and guide them through all related care services until full resolution of disease. A trained Contact Tracer (To be Named) will ensure timely and efficient contact tracing protocols are followed. PI Ismail will be monitoring all operations for the research project. The MSHC practice sites are all a part of the UI Health umbrella. However, because there are different sites, the project manager will also be monitoring the research project at each site. For recruitment, all staff at the MSHC evaluating patients will be trained to recruit subjects for this research study in a series of WebEx meetings. They will be trained to recruit subjects both during in-person visits and/or through telehealth visits. For specimen collection, there will be three options for subjects. Personnel collecting specimens will be trained by the medical director at each of the 14 sites, overseen by Co-I Jasenof.

In addition to these measures, six senior UIC scientist-clinicians not involved with the proposed project who are all leading COVID-19 clinical care and research at UIC have agreed to join with six to-be-named community members who are survivors of COVID-19 to form a Community and Scientific Advisory Board. The board will provide formative evaluation of study milestones in

relation to the timeline, oversight over all study procedures and staffing, and will recommend changes, as needed.

## **11.0 Data and Safety Monitoring**

All data will be housed in a HIPAA compliant secure platform in the UIC COVID-19 Unit of the Center for Biostatistical Development. Co-I Basu will save, convert, and transfer any and all data into formats that are required by the CDCC, NIH, and OCC. Co-I Basu will integrate data generated by a single RedCap system from the Microbiology (viral data) and Applied Health Sciences (all other self-report and health record data) laboratories of PIs, Ismail and Ismail, respectively. Co-I Basu will be responsible for all secure data storage from all study samples and subsamples, management, analyses, and transfer to the relevant public officials in compliance with all Federal, State, County, City and UIC policies and standards. The UIC Office for the Protection of Research Subjects Human Subjects Protection Program (OPRS) partners with the UIC Center for Clinical and Translational Science (CCTS) to promote community engaged human subjects research. This team meets twice monthly and includes members from faith-based organizations, grassroots and large-scale nonprofits/NGOs, higher education and research institutions, as well as healthcare settings. The CCTS Community Engagement Board will monitor data safety and reporting in collaboration with the NIH CDCC. We will also collaborate with the SEBI program (NOT-OD-20-119) to conduct additional formative analyses to ensure the safety of our study population.

### ***Breeches of Confidentiality and Adverse Events***

Any data breeches will be reported on the OPRS Adverse Events Reporting form and also reported immediately to the UIC HIPPA Officer and to the NIH. All procedures for informing subjects of the breach and any other recommended actions by the UIC HIPPA Officer will be strictly adhered to. Any other breeches of confidentiality will be reported immediately to the NIH and to OPRS via the Adverse Events Reporting form and all subsequent guidelines and recommendations will be strictly adhered to. Adverse events, such as the death or hospitalization of a subject during the study due to COVID-19 or related complications, will also be reported to the NIH and OPRS on the Adverse Events Reporting form and all subsequent guidelines and recommendations will be strictly adhered to.

## **12.0 Statistical Considerations**

### ***Sample Size and Attrition***

Statistical analyses were described in Section 9. Our target sample size is 7000 subjects (adults and children), with four nasal swab collections per subject (28,000 samples) and two self-report interviews for each adult subject. The historical-average positivity rate of COVID-19 within Chicago is 9.79% and 8.68% in Cook County. Some members of our Aim 1 cohort are higher-risk (as they are already seeking care and have access to testing), but testing uptake in the other cohorts is expected to reduce the test positivity rate. Our study is expected to have approximately 80% power to detect a 1% change in positivity rate at 0.05 significance level. We will be collecting nasal swab samples at 1 time point. Based on our past experience with large-scale epidemiological studies (PI Ismail), we will conservatively anticipate an attrition rate of 25% over the 28-day period where blood and swabs collections will be requested. This effective sample size of 5250 will offer more than 80% power to detect a small effect size measured by  $f^2=0.004$  for the multivariate (regression) analyses planned for this study.

Our sampling approach combines sentinel, contact tracing, and community surveillance methods to recruit and test a total of 7000 persons, of which we anticipate at least 671 will test positive. This estimate was based on the historical-average positivity rate of COVID-19 within Chicago (9.79%) and Cook County (8.68%). These rates were taken from the Illinois Department of Health Website on July 29, 2020. Planning conservatively for a 25% attrition rate, this still leaves 503 test-positive cases for each of which we would have four distinct, repeated-measures sample collections and self-report data collection observations. It is our opinion that our plans for the regression analyses and advanced machine learning analyses would be adequately powered. We have repeated our power and sample size calculations with a variety of different baseline positivity rates and found the proposed study to have sufficient power to detect small effect sizes.

Given our anticipated attrition rate of 25%, 10% of 503 test-positive cases = 50 cases. We believe that this would be a large enough sample for simple descriptive subgrouping and bivariate correlational analyses.

### ***Breaches of Confidentiality and Adverse Events***

As described in the previous section, any data breaches will be reported on the OPRS Adverse Events Reporting form and also reported immediately to the UIC HIPPA Officer and to the study sponsor, NIH. All procedures for informing subjects of the breach and any other recommended actions by the UIC HIPPA Officer will be strictly adhered to. Any other breaches of confidentiality will be reported immediately to the NIH and to OPRS via the Adverse Events Reporting form and all subsequent guidelines and recommendations will be strictly adhered to.

It is anticipated that at least 10% of our sample will test positive for COVID-19. If a subject tests positive for COVID-19, the diagnosis will be confirmed by the study physician at the MSHC practice site where the subject delivered the nasal swab specimen. The subject will be followed medically according to standard medical care procedures by his/her/their primary care provider or, if the subject does not have a primary care provider, by an attending physician at the MSHC practice site. The MSHC practice sites do not discriminate based on nationality/immigration status, ability to pay, or proof of insurance. In tandem with medical care, the trained study contact tracer will initiate the contact tracing interview and will also provide follow up through ongoing communication about symptoms and health status using the mHealth Suite (or by telephone, if the subject is not using the mHealth Suite). If a subject reports one or more symptoms that indicate the need for emergency care, the subject will be contacted immediately and advised to call 911 or go to the nearest Emergency Department. PI Ismail and co-I Jasenof will follow up with the subject and/or Emergency Department to ensure that appropriate emergency care is being provided. Other adverse events, such as the death or hospitalization of a subject during the study due to COVID-19 or related complications, will also be reported to the NIH and OPRS on the Adverse Events Reporting form and all subsequent guidelines and recommendations will be strictly adhered to.

It is also possible that a student or staff member working on this project may contract COVID-19 during the performance period, either via contact with an infected person, surface, or specimen during work for the project or elsewhere in the community. This risk will be mitigated by requiring all staff to take the UIC COVID-19 safety training course, the Stanford COVID-19 course for healthcare professionals <https://www.coursera.org/learn/covid-19-training-healthcare> and the UIC Institutional Biosafety course. Appropriate PPE will be provided by the Ismail or Ismail lab and will include an N95 mask, face shield and scrubs. If a student or staff member

exhibits symptoms and/or tests positive for COVID-19 through the university COVID-19 surveillance system or other testing process, the student or staff member will be referred to University Health Services and the UIC Contact Tracing program for standard care follow-up.

## **13.0 Regulatory Requirements**

### **13.1 Informed Consent**

The consent and enrollment approach will be staged and tailored according to how participants are recruited into the study and according to which components of the study they decide to undertake. This approach will be taken to minimize coercion, to maximize the utility of data provided in the study, and to ensure that participants fully understand and consent to each aspect of the study in which they are participating.

**Type 1 Consent Process:** Participants seeking care on-site from Mile Square Health Center will be consented to participate in all aspects of the study (i.e., telephone interviews, data from their interaction with the mHealth Suite, and COVID-19 nasal swab diagnostic testing). These individuals will be consented and enrolled in person by the Mile Square practice site health provider via a consent form (for adults ages 18 and over) and a parental consent form and child assent form (for children under the age of 18). Their understanding will be assessed via the questions include at the end of the consent form. All children will only be assented (via written consent) with parental permission in person on-site at the Mile Square clinics. The consent form for children and adults will be done under clinical supervision of the research team (clinical research coordinator, research assistant and medical staff). The paper consent forms completed on-site will be picked up daily by the study coordinator along with the biospecimens and transported to the respective laboratories (PI Ismail lab for consent form storage in a locked cabinet within a locked lab room and PI Ismail lab for biospecimen processing and storage. (see Adult consent form, Parental Permission Form and Child Assent Form.). The participants will have an opportunity to consent for the sharing and linking (via telephone number) of their self-report symptom data from the Stoplight App with UIC, the Duke Clinical Research Institute (DCRI), and the Illinois Department of Public Health. A contact phone number for a research assistant will be provided for technical assistance in uploading and using the apps and videos.

**Type 2 Consent Process:** For subjects who are interested in completing the study remotely (home collection) via using the apps in the mHealth Suite, consent will be obtained using a digital form on the Enrollment App (see Enrollment App Digital Consent form for Adults Only). Participants who phone the study contact number or upload and order a self-testing kit via the smartphone Enrollment app on their own, will be initially identified by the research assistant receiving the phone call or text notification from the app. These subjects will be recruited or interviewed by phone by the research assistant using a script (pls see the information sheet). After individuals indicate consent via the app by touching the "I accept" button, the app will then prompt an electronic consent review and Q&A phone call from the study staff. The study staff will talk them through the digital consent process, orient them to the mHealth Suite of study apps and videos, and ask them if they have questions and assess their understanding with true-false questions about the mhealth app part of the study (questions are located at the bottom of the Enrollment App Digital Consent Form). Via the Enrollment App, these subjects will have an opportunity to digitally (electronically) consent for the sharing and linking (via telephone number) of their self-report symptom data from the Stoplight App with UIC, DCRI and the Illinois Department of Public Health. A contact phone number for a research assistant will be provided



for technical assistance in uploading and using the apps and videos. The nasal swab self-collection kit will be picked up by those subjects at a local community site or at the nearest MSHC practice site. Instructions on how to read and electronically sign the consent form will be included also in the kit. When the subject returns the nasal swab sample at the nearest MSHC practice site, the subject will deliver the kit to the front desk security guard, store the kit appropriately for pick-up.

If, through our consent and outreach phone call, subjects originally participating only in the mHealth component of the study decide that they are interested in testing of themselves and/or a family member for COVID-19, they will be provided with a location of the nearest MSHC practice site or community site where they may pick up the requisite number of nasal swab self-testing kits, each of which will also contain the paper consent form that does require signatures and will be included in the self-testing kit. As described in the previous section, the signed paper consent form will be returned with the biospecimen that the subject provides when dropping off the kit at a nearby MSHC practice site.

We anticipate that there will be another group of participants that utilize the mHealth Suite but never choose to call the study telephone number, do not seek care from a Mile Square Health Center practice site, and never choose to undertake COVID-19 diagnostic testing. These participants will be consented for data sharing only via the Enrollment App, which will: (a) guide them through the consent and enrollment process, prompt a verbal consent review and Q&A phone call from study staff, and (b) link them to the remaining aspects of the entire mHealth COVID-19 Literacy and Feedback Suite. The only identifying information that will be collected from this group of mHealth-only participants will be their telephone numbers. The reason we will need this information is that the telephone number will serve as a means of contacting participants and as a means of linking the nasal swab samples to the data reported via the apps within the mHealth Suite for the other participant categories that do choose to participate in these aspects of the study.

Any healthcare provider at the 14 MSHC practice sites who anticipates that they may be consenting subjects, along with the lab technician and research assistants completing the telephone interviews, will be personally trained to consent subjects by the PI, Nahed Ismail. This training will consist of an initial reading of the consent form, followed by a quiz to assess the staff's understanding of the study procedures, the contents of the consent form and their understanding of the consenting process. Team members will be encouraged to consent each other during a breakout session, which will occur during the same training session. These trainings will consist of role plays (including acceptance and refusal of the consent process and during the over the phone interviews). All members will be trained until there are no further questions about conducting the interviews with participants. Additionally, each team member involved in consenting subjects will complete the Stanford online training on applying wearing an appropriate level of PPE if they need to the MSHC's to deliver consent forms or study flyers <https://www.coursera.org/learn/covid-19-training-healthcare> as well as the institutional biosafety course and campus COVID-19 safety training. Appropriate PPE will be provided by the Ismail or Ismail lab and will include an N95 mask, face shield and scrubs.

Physical consent documents will be stored in a locked file cabinet in the lab of PI Ismail (AHSB 322), separate from all other information for at least two years.

For Spanish-speaking participants, consent forms will be provided in Spanish.

A summary of consent approaches and procedures is presented in the table below.

	Optional Procedure	Non-Optional Procedure	Survey/Questionnaire	Consent Form
Minor	Collection of Nasal swabs if it is done remotely via contact tracing or community recruitment via mobile app.	Collection of Nasal swabs if they visit one of the FQHCs as patients (children with symptoms)	Yes, collected via parents	<p># Older children will be assented for nasal nares testing in person using a written assent form at the MSHC sites. Children will be required to either read or hear the information on the consent form, understand it and provide verbal and written assent (if they are able to read and write).</p> <p>#Children unable to read will be assessed for assent verbally and/or through observation of their body language and vocalizations regarding their willingness to have their nasal swab sample collected.</p> <p>#All children will only be assented with parental consent in person on-site at a practice site.</p>
Adults		Collection of Nasal swabs for all (symptomatic and asymptomatic)	Yes	Full consent form that include specific survey questionnaire
Recruitment via clinical site visit				<p><b>Type I consent process:</b> These individuals will be consented and enrolled in person by the Mile Square practice site health provider via a consent form (for adults ages 18 and over) and a parental consent form and child assent form (for children under the age of 18). Their understanding will be assessed via the questions include at the end of the consent form.</p>
Recruitment via contact tracing				<p><b>Type II consent process:</b> For subjects who are interested in completing the study remotely, a staged consent process that involves verbal, written, and waiver-of-signature consent (for the deidentified data collected via the mHealth Suite, only) will be vital to ensuring the ethics, feasibility of completion, and human protections necessary for this study.</p>

Recruitment via Wepapp and community champions				<b>Type 3 Consent Process</b> (waiver of signed consent for the provision of deidentified data via the mHealth Suite): For those choosing only to interact with the apps in the mHealth Suite and not participate in the COVID-19 nasal swab-based diagnostic testing, the telephone interviews consent will be obtained using a digital form on the Enrollment App.
--	--	--	--	--

## 13.2 SUBJECT CONFIDENTIALITY

The multiple efforts in place to protect and maintain subject confidentiality have already been described elsewhere in this proposal (Refer to Sections 7 and 12). The PIs and Co-I Basu, along with Co-I Basu's research assistant, will have access to the data. Data will be analyzed and shared via REDCap with the Illinois Department of Public Health following all applicable laws and regulations. By law, the nasal swab specimens, COVID-19 diagnostic testing results, and contact tracing data will retain identifiers (name, phone number, date of birth) so that it may be appropriately transferred to the Illinois Departments of Public Health, upon request. As described elsewhere, the self-report interview data and mHealth data will be collected via REDCap, a secure password-protected and encrypted data storage and management system. These data will be coded with meaningless, numeric codes that are linked to a list containing the participants' names and contact information. This contact list will be stored separately in a different password protected folder within the server, with paper versions of the contact information collected at the MSHC practice sites stored in a locked cabinet in the PI's lab (AHSB Room 322). Identifiers will be destroyed along with the specimens after the project ends and manuscripts have been published. Personally identifiable data for the biological specimens and the contact tracing interview data is being required by the Sponsor in collaboration with the Illinois Departments of Public Health. A Certificate of Confidentiality will not be required.

## 13.3 UNANTICIPATED PROBLEMS

Any data breaches will be reported on the OPRS Adverse Events Reporting form and also reported immediately to the UIC HIPPA Officer and to the study sponsor, the NIH. All procedures for informing subjects of the breach and any other recommended actions by the UIC HIPPA Officer will be strictly adhered to. Any other breaches of confidentiality will be reported immediately to NIH and to OPRS via the Adverse Events Reporting form and all subsequent guidelines and recommendations will be strictly adhered to. Adverse events, such as the death or hospitalization of a subject or study staff member during the study due to COVID-19 or related complications, will also be reported to NIH and to OPRS on the Adverse Events Reporting form and all subsequent guidelines and recommendations will be strictly adhered to.

## 14.0 References

1. U.S. CENTERS FOR DISEASE CONTROL.(2020). *DATA TRACKER: COVID-19 CASES AND DEATHS BY STATE*. RETRIEVED AUGUST 31, 2020 FROM [HTTPS://COVID.CDC.GOV/COVID-DATA-TRACKER#CASES](https://COVID.CDC.GOV/COVID-DATA-TRACKER#CASES)
2. Cook County Department of Public Health. (2020). *Covid-19 Information*. <https://cookcountypublichealth.org/communicable-diseases/covid-19/>
3. Illinois Department of Public Health. (2020). *Covid-19 Statistics*. <http://www.dph.illinois.gov/covid19/covid19-statistics>
4. Hawkins, D. (2020). Differential occupational risk for COVID-19 and other infection exposure according to race and ethnicity. *American Journal of Industrial Medicine*. <https://doi.org/10.1002/ajim.23145>
5. Kendi, I.X. (2020). Stop blaming Black people for dying of the Coronavirus. *The Atlantic*. <https://www.theatlantic.com/ideas/archive/2020/04/race-and-blame/609946/>.
6. UI Health (2020). *UI Health MSHC Community Needs Assessment Report*. <https://hospital.uillinois.edu/about-ui-health/community-commitment/community-assessment-of-health-needs-ui-can>.
7. Khare, N., Bhatia, I. & Trocino, A. (2020). *Chicago federally qualified health centers capacity report*. UIC School of Public Health. <https://publichealth.uic.edu/news-stories/chicago-federally-qualified-health-centers-capacity-study/>
8. Tenforde, M. W., Kim, S.S., Lindsell, C.J., Rose, E.B., Shapiro, N.I., Files, C., Gibbs, K., Erickson, H.L., Steingrub, J.S., Smithline, H.A., Gong, M.N., Aboodi, M.S, Exline, M.C., Henning, D.J., Wilson, J.G., Khan, A., Qadir, N., Brown, S.M., Peltan, I.D., ... Feldstein, L.R. (2020). *Symptom duration and risk factors for delayed return to usual health among outpatients with COVID-19 in a multistate health care systems network—United States, March–June 2020*. Centers for Disease Control and Prevention-Morbidity and Mortality Weekly Report. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6930e1.htm>
9. Balcazar, F.E., TaylorIsmail, R.R., Kielhofner, G.W., Tamley, K., Benziger, T., Carlin, N., & Johnson, S. (2001). Participatory Action Research: General Principles and a Study with a Chronic Health Condition. In L.A. Jason, C.B. Keys, Y. Suarez-Balcazar, R.R. TaylorIsmail, & M.I. Davis (Eds.), *Participatory Community Research: Theories and Methods in Action* (pp. 18-19). Washington DC: American Psychological Association
10. Molesworth, A. M., Ndhlovu, R., Banda, E., Saul, J., Ngwira, B., Glynn, J. R., Crampin, A. C., & French, N. (2010). High accuracy of home-based community rapid HIV testing in rural Malawi. *Journal of acquired immune deficiency syndromes* (1999), 55(5), 625–630. <https://doi.org/10.1097/QAI.0b013e3181f98628>

11. Sweat, M., Morin, S., Celentano, D., Mulawa, M., Singh, B., Mbwapambo, J., Kawichai, S., Chingono, A., Khumalo-Sakutukwa, G., Gray, G., Richter, L., Kulich, M., Sadowski, A., Coates, T., & Project Accept study team (2011). Community-based intervention to increase HIV testing and case detection in people aged 16-32 years in Tanzania, Zimbabwe, and Thailand (NIMH Project Accept, HPTN 043): a randomised study. *The Lancet. Infectious diseases*, 11(7), 525–532. [https://doi.org/10.1016/S1473-3099\(11\)70060-3](https://doi.org/10.1016/S1473-3099(11)70060-3)
12. Njau, B., Watt, M. H., Ostermann, J., Manongi, R., & Sikkema, K. J. (2012). Perceived acceptability of home-based couples voluntary HIV counseling and testing in Northern Tanzania. *AIDS care*, 24(4), 413–419. <https://doi.org/10.1080/09540121.2011.608796>
13. Choko, A. T., Desmond, N., Webb, E. L., Chavula, K., Napierala-Mavedzenge, S., Gaydos, C. A., Makombe, S. D., Chunda, T., Squire, S. B., French, N., Mwapasa, V., & Corbett, E. L. (2011). The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. *PLoS medicine*, 8(10), e1001102. <https://doi.org/10.1371/journal.pmed.1001102>
14. MacPherson, P., Lalloo, D. G., Choko, A. T., Mann, G. H., Squire, S. B., Mwale, D., Manda, E., Makombe, S. D., Desmond, N., Heyderman, R., & Corbett, E. L. (2012). Suboptimal patterns of provider initiated HIV testing and counselling, antiretroviral therapy eligibility assessment and referral in primary health clinic attendees in Blantyre, Malawi. *Tropical medicine & international health : TM & IH*, 17(4), 507–517. <https://doi.org/10.1111/j.1365-3156.2011.02946.x>
15. Nelson, A. K., Caldas, A., Sebastian, J. L., Muñoz, M., Bonilla, C., Yamanija, J., Jave, O., Magan, C., Saldivar, J., Espiritu, B., Rosell, G., Bayona, J., & Shin, S. (2012). Community-based rapid oral human immunodeficiency virus testing for tuberculosis patients in Lima, Peru. *The American journal of tropical medicine and hygiene*, 87(3), 399–406. <https://doi.org/10.4269/ajtmh.2012.12-0036>
16. Sabapathy, K., Van den Bergh, R., Fidler, S., Hayes, R., & Ford, N. (2012). Uptake of home-based voluntary HIV testing in sub-Saharan Africa: a systematic review and meta-analysis. *PLoS medicine*, 9(12), e1001351. <https://doi.org/10.1371/journal.pmed.1001351>
17. Mantell, J. E., DiCarlo, A. L., Remien, R. H., Zerbe, A., Morris, D., Pitt, B., Nkonyana, J. P., Abrams, E. J., & El-Sadr, W. (2014). 'There's no place like home': perceptions of home-based HIV testing in Lesotho. *Health education research*, 29(3), 456–469. <https://doi.org/10.1093/her/cyu004>
18. Kumwenda, M., Munthali, A., Phiri, M., Mwale, D., Gutteberg, T., MacPherson, E., Theobald, S., Corbett, L., & Desmond, N. (2014). Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. *AIDS and behavior*, 18 Suppl 4(Suppl 4), S396–S404. <https://doi.org/10.1007/s10461-014-0817-9>
19. Makusha, T., Knight, L., Taegtmeier, M., Tulloch, O., Davids, A., Lim, J., Peck, R., & van Rooyen, H. (2015). HIV self-testing could "revolutionize testing in South Africa, but it has got to be done properly": perceptions of key stakeholders. *PloS one*, 10(3), e0122783. <https://doi.org/10.1371/journal.pone.0122783>
20. Choko, A. T., MacPherson, P., Webb, E. L., Willey, B. A., Feasy, H., Sambakunsi, R., Mdolo, A., Makombe, S. D., Desmond, N., Hayes, R., Maheswaran, H., & Corbett, E. L. (2015).

Uptake, Accuracy, Safety, and Linkage into Care over Two Years of Promoting Annual Self-Testing for HIV in Blantyre, Malawi: A Community-Based Prospective Study. *PLoS medicine*, 12(9), e1001873. <https://doi.org/10.1371/journal.pmed.1001873>

21. van Heerden, A., Harris, D. M., van Rooyen, H., Barnabas, R. V., Ramanathan, N., Ngcobo, N., Mpiyakhe, Z., & Comulada, W. S. (2017). Perceived mHealth barriers and benefits for home-based HIV testing and counseling and other care: Qualitative findings from health officials, community health workers, and persons living with HIV in South Africa. *Social science & medicine* (1982), 183, 97–105. <https://doi.org/10.1016/j.socscimed.2017.04.046>

22. Gichangi, A., Wambua, J., Mutwiwa, S., Njogu, R., Bazant, E., Wamicwe, J., Wafula, R., Vrana, C. J., Stevens, D. R., Mudany, M., & Korte, J. E. (2018). Impact of HIV Self-Test Distribution to Male Partners of ANC Clients: Results of a Randomized Controlled Trial in Kenya. *Journal of acquired immune deficiency syndromes* (1999), 79(4), 467–473. <https://doi.org/10.1097/QAI.0000000000001838>

23. Njau, B., Covin, C., Lisasi, E., Damian, D., Mushi, D., Boule, A., & Mathews, C. (2019). A systematic review of qualitative evidence on factors enabling and deterring uptake of HIV self-testing in Africa. *BMC public health*, 19(1), 1289. <https://doi.org/10.1186/s12889-019-7685-1>

24. Frola, C. E., Zalazar, V., Cardozo, N., Vázquez, M. L., Arístegui, I., Lucas, M., Gun, A., Cahn, P., & Sued, O. (2020). Home-based HIV testing: Using different strategies among transgender women in Argentina. *PloS one*, 15(3), e0230429. <https://doi.org/10.1371/journal.pone.0230429>

25. Ganguli, I., Bassett, I. V., Dong, K. L., & Walensky, R. P. (2009). Home testing for HIV infection in resource-limited settings. *Current HIV/AIDS reports*, 6(4), 217–223. <https://doi.org/10.1007/s11904-009-0029-5>

26. UIC News (2020). School of Public Health to Co-Lead Contact Tracing in Chicago. UIC News article downloaded from the World Wide Web at <https://publichealth.uic.edu/news-stories/sph-to-co-lead-contact-tracing-in-chicago/> on August 31, 2020.

27. UIC News (2020, July 8). Contact Tracing for Communities of Color. Retrieved August 31, 2020 from <https://publichealth.uic.edu/news-stories/contact-tracing-for-communities-of-color/>

28. Chen, Y. & Lanjuan, L. (2020). SARS-CoV-2: virus dynamics and host response. *Lancet Infectious Diseases*, 20(5): 515–516. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7156233/>

29. To, K.K., Tsang, O.T., Leung, W., Tam, A.R., Wu, T., Lung, D.C., Yip, C.C., Cai, J.P., Chan, J.M., Chik, T.S., Lau, D.P., Choi, C.Y., Chen, L.L., Chan, W., Chan, K., Ip, J.D., Ng, A.C., Poon, R.W., Luo, C.,...Yuen, K. (2020). Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. *Lancet Infectious Diseases*, 20(5):565-574

30. Jason, L.A., Richman, J.A., Rademaker, A.W., Jordan, K.M., Plioplys, A.V., Ismail, R.R., McCready, W., Huang, C.F. & Plioplys, S. (1999). A Community-Based Study of Chronic Fatigue Syndrome. *Arch Intern Med*. 1999;159(18):2129–2137. doi:10.1001/archinte.159.18.2129

31. Rappaport, J. (1994). Empowerment as a guide to doing research: Diversity as a positive value. In E.J. Trickett, R.J. Watts, et al (Eds.), *Human diversity: Perspectives on people in context* (359-382). San Francisco, CA: Jossey-Bass Inc.