Scale Up Counts Protocol Summary
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SCALE-UP Counts: A health information technology approach to increasing COVID-19 testing in elementary and middle schools serving disadvantaged communities

Protocol Summary

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University of Utah IRB #:	IRB_00143340
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Background and Introduction

Racial/ethnic minority and low socioeconomic status (**SES**) populations suffer profound health inequities across a wide variety of conditions as well as a disproportionate burden of the negative health consequences of the COVID-19 pandemic. Latinos make up ~14% of the Utah population vs. ~21% of Utah's COVID-19 cases (50% higher) and the case rate is over 3-fold higher in neighborhoods characterized by high vs. low deprivation.

In the Utah 2020-2021 school year, there have been 36,484 school-associated cases of COVID-19. Our ongoing partnerships with the Utah Department of Health (**UDOH**) allows us to access real-time information on "hotspot schools" across the state. One of our Utah school district partners, Granite School District (n=85 schools), currently has the 3rd highest number of cases of COVID-19 and 45% of its schools have a student population with >50% eligible to receive free/reduced lunch and 60% have a student population that is >50% ethnic minority. Schools bear a large part of the burden of managing COVID-19 testing and communicating with parents about testing their children. Few schools in Utah have information technology systems in place to support systematic communication with parents about student COVID-19 testing and tracking testing outcomes.

Through an existing RADx-UP grant (UL1TR002538-03S4), our team developed a text messaging and health navigator infrastructure that is now deployed in federally-qualified health centers across Utah. We chose to use text messaging because it is widely available in underserved communities, with 97% of individuals with an annual income <$30,000 and 96% with educational attainment of high school or less having a phone that can text.

Additionally, the grant application and ERICA application are consistent in terms of study objectives/purpose, study design, study interventions/procedures, and study population.

Purpose and Objectives

Overview to Proposed Program:

This project will address key testing challenges in schools by building on our collaborations with public school districts, private schools, charter schools and with UDOH on COVID-19 testing and existing infrastructure. While we are focused on COVID-19 testing, in the case that the COVID-19 vaccination becomes more relevant or is the priority of the school, we are able to focus our intervention on the vaccine as well. We will work closely with schools and the Utah public health system to implement and test a shovel-ready and scalable health information technology approach that delivers automated text messages (**TMs**) to students' parents and faculty/staff members around COVID-19 testing. In addition, some students and faculty/staff will receive a health navigator (**HN**) follow-up to ensure that tests are completed.

HN will be community members who have been trained in case management. Families (both of students and faculty/staff members) will be offered the recently FDA-approved in-home serial testing approach if accessing in-person testing is a challenge.

We will employ a Sequential Multiple Assignment Randomized Trial (SMART) design using short time frames (<1 month) and iterative evaluation cycles. The proposed trial will compare the efficacy of TM versus usual care as an initial intervention. Among participants randomized to the TM condition, during each 2-3 week cycle, participants who report COVID-19 symptoms or contact with someone with COVID-19 will be evaluated and classified as compliant (if COVID-19 test completed) or non-compliant (if no COVID-19 test is completed or no response received). Non-compliant participants will then either continue receiving TM or additionally receive HN (TM+HN) for the remainder of that cycle, depending on the condition to which they were randomly assigned at the beginning of the study.

Research Question #1: Impact of an information technology and health navigator intervention for COVID-19 testing for underserved and vulnerable populations: Does text messaging vs. text messaging plus health navigator differentially:

(a) Increase the proportion of students and/or faculty and staff members tested out of those who meet criteria for testing?

(b) Decrease missed school days?

(c) Decrease parent-reported challenges obtaining COVID-19 testing for their child?

Approach and Design #1:

We will conduct a Sequential Multiple Assignment Randomized Trial (SMART) that compares TM versus usual care/control in a first randomization of the study. During each cycle of the study, we will evaluate compliance to the TM intervention. Non-compliant participants will then receive their Phase 2 condition of continued TM or TM+HN to test whether "stepping up" to HN improves outcomes for those not responding to the first-line intervention of TM. All randomizations will take place on the individual level at the beginning of the study; participants will be randomized to the initial intervention (TM vs. usual care; Phase 1 Randomization), and TM participants will also be randomized to the Phase 2 condition (TM or TM+HN) which they would receive during cycles during which they are non-compliant.

This project is a Sequential Multiple Assignment Randomized Trial (SMART) that will be conducted with approximately 20,000 staff, parent, and student participants across 30 schools.

Research Question #2: Implementation outcomes: What implementation barriers and facilitators are identified, including by students, faculty/staff members, parents, schools, and health navigators

Approach and Design #2: We will conduct a mixed-methods evaluation to understand implementation effectiveness outcomes as well as characteristics of both schools and students/ families that may influence intervention effects and implementation outcomes.

Research Question #3: Moderators of intervention effects: What are the student/family socio-demographic and school characteristic moderators of SCALE-UP Counts effects?

Study Population

Age of Participants: Participants of all ages

Sample Size:
At Utah:
All Centers: approx. 20,000

Inclusion Criteria:
We will partner with up to 30 elementary, middle and high schools in several school districts including the ones outlined below (n=67 eligible schools; see **Table 1**) as well as private and charter schools in the surrounding area. We will focus primarily on elementary school students who currently are not recommended to receive the COVID-19 vaccine.

Table 1. Example Participating Schools

District	# of Schools Meeting Underserved Criteria	# of Students	Student Characteristics
Granite	48	26,420	• ~60% eligible for free/reduced lun • ~64% are ethnic minorities
Salt Lake City	19	7,828	• ~77% eligible for free/reduced lun • ~76% are ethnic minorities

Students

- Attends school at any of the participating elementary, middle, or high schools from the districts, charters, or private schools the research team is working with.

Parents

- Legal guardian/parent of the student.

- Has a functioning cellular phone that can receive calls and text messages.

School Staff

- Works at any of the participating elementary or middle schools from the districts, charters, or private schools the research team is working with.

Exclusion Criteria:

None

Design

Randomized Trial
Prospective Social/Behavioral Intervention or Experiment

Study Procedures

Recruitment/Participant Identification Process:

The proposed study will partner with elementary and middle schools from Utah school districts including the Granite School District and Salt Lake City School District, as well as private and charter schools in the surrounding area. The administration of the partnering schools and schools districts will have the option to follow an "opt-in" or "opt-out" enrollment procedure as outlined below:

"Opt-out" Enrollment Procedure:

The research team anticipates that SCALE-UP Counts will receive a waiver of documentation of consent from the IRB. All students who attend partnering schools will be enrolled, with parents/guardians provided with a website link to view a study information with details about the study and information on compensation (up to $25 per completed survey) and how to opt out. Staff at the participating schools/districts who wish to participate will also be enrolled and receive the same information for the website study information letter and opt-out information. Informational flyers with contact information will be available at schools in English and Spanish. A social media posting will be made available to all participating schools to share on their social media accounts. The social media post directs people to the study website, similar to the informational flyers. All parents/guardians who meet criteria (i.e., have a functioning cellular phone that can receive calls and text messages) will be eligible to be randomized to text messaging (TM) or usual care groups. Participants who are randomized to text messaging and who are deemed non-compliant will be randomized again to text messaging (TM) or text messaging and health navigator (TM + HN). Participants who stop attending an enrolled school will be removed from the intervention but will continue to receive follow-up surveys. These participants will have the option to opt out by emailing the study team. The study team's email will be provided in the REDCap surveys.

"Opt-In" Enrollment Procedure:

For those partnering schools and districts who wish to follow the “opt-in” enrollment procedure, the district administration will send a survey to parents/guardians and school staff via e-mail or other communication method with the same study information outlined above (i.e. website link, study information letter, social media post etc.) and the option to opt-in to the study. Upon survey completion, contact information of those parents/guardians and school staff who are willing to participate will be send directly to the study team.

The proposed study will also partner with Utah Department of Health (UDOH) to obtain lists of schools and districts in Utah that request free COVID-19 home test kits from UDOH. The study team will reach out to these schools and districts in an effort to pair the study with the schools' test kit distribution. The study team will not provide the district/school with COVID-19 home test kits unless requested. Schools/districts will utilize COVID-19 home test kits provided to them by UDOH and the proposed study will work in parallel with these efforts. Districts/schools recruited in partnership with UDOH will still need to meet the criteria and will be provided with the same website link, opt-out options, and flyers as described above.

Informed Consent:

Description of location(s) where consent will be obtained:

For schools implementing the "opt-out" enrollment procedure, students will be sent home with the study flyer (attached) to inform their parents/guardians about the study procedures. Study flyers will also be distributed to faculty/staff of the participating schools. The study website will act as the study cover letter and will provide information on study procedures and opt out options. The website link will be provided to every potential participant through a text message. For schools implementing the “opt-in” enrollment procedure, district administration will send a survey containing study information to parents/guardians and school staff with the option to “opt-in” to the study. Contact information for parents/guardians and school staff who have opted-in to the study will be provided to the study team via REDCap. For research question #1: n/a waiver of documentation of consent requested for parents/guardians, school staff, and health navigators who are invited to participate in the study will have an opportunity to opt in or out of the study. For research question #2: n/a waiver of documentation of consent requested for parents/guardians, school staff, and health navigators who are invited to participate in qualitative interviews (research question #2) and to complete further questionnaires about their experience with SCALE-UP Counts, they will provide verbal consent prior to the interview and questionnaire completion. This will be completed over the phone and/or electronically.

Description of the consent process(es), including the timing of consent:

Informed Consent and Assent Procedures for research question #1: Prior to study activities, all potential participants and their parents/guardians will receive the relevant study information website link to review and/or a survey link from district administration with relevant study information. The study information website link provided will cover the basic elements of consent. Faculty/staff members and parents/guardians of students (if the student is <18 years of age) will have the opportunity of opting their child/themselves into or out of participating in the current study. Parents/guardians of students will receive a study cover letter website link with information about participation. Upon reviewing the website/cover letter,

parents/guardians will have an opportunity to opt-in or -out of participation. Those who are participating will receive the consent and parental permission cover letter/website, which are within the same document. Children who are 8 years of age or older will receive the assent cover letter.. A waiver of consent/assent has been similarly granted for our other studies, including one led by MPI Wu of a cluster-randomized trial in Utah schools. Informed Consent and Assent Procedures for research question #2: For students, parents/guardians, school staff, and health navigators who are invited to participate in qualitative interviews and to complete further questionnaires about their experience with SCALE-UP Counts, they will provide verbal consent prior to interview and questionnaire completion. See interview guide documents for verbal consent wording. We will use the NIH RADx-UP Tier 1 CDEs and/or modify them for use with pediatric populations to assess socio-demographics, housing, employment, and insurance, testing, and symptoms. We have the capacity to accommodate data harmonization and sharing with the RADx CDCC, including through infrastructure established through our currently-funded RADx-UP grant (UL1TR002538-03S4). We will also use items assessing social determinants of health from the PhenX Toolkit (e.g., family income, birthplace, access to health services, health literacy, concentrated poverty) and COVID-19 specific constructs (e.g., vulnerability and exposure to COVID-19, COVID-19 knowledge, attitudes, and avoidant behaviors). No personal identifiers are collected which is why we applied for a waiver of documentation of consent to achieve this research aim. Personal identifiers are asked when completing the RADx-UP Tier 1 Common Data Elements surveys. Prior to completing RADx-UP questionnaires, staff and parents/guardians will be provided with detailed consent information specifically pertaining to the collection and sharing of the data collected on these questionnaire with the Duke Clinical Research Institute. Participants determine the level of PHI they wish to provide and they are not required to provide PHI to complete surveys. Participants are asked if they consent to collecting identifiable information to be shared with the Duke Clinical Research Institute including (but not limited to) name, date of birth, address, social security number, sociodemographic information and if they wish to be contacted about future research which is why we applied for a waiver of documentation of consent to achieve this research aim. See RADx-UP ICF document for consent language. Informed Consent and Assent Procedures for COVID-19 test results provided by Ellume at-home test application: Users who download and utilize the app for testing/test result purposes agree to privacy policy and terms prior to testing within the Ellume app.

Procedures:

Enrollment/waiver of documentation of consent: For partnering schools implementing the "opt-out" enrollment procedure, all students who attend partnering schools will be enrolled, with parents/guardians provided with a study information through a website link with details about the study and information on compensation (up to $25 per completed survey) and how to opt out. Staff at these participating schools/districts who wish to participate will also be enrolled and receive the same website link for study information and opt-out information. All parents/guardians who meet criteria (i.e., have a functioning cellular phone that can receive calls and text messages) will be eligible to be randomized to text messaging (TM) or usual care groups. Participants who are randomized to text messaging and that are deemed non-compliant will additionally receive a health navigator (TM + HN) if randomized to that condition.

For those partnering schools and districts who wish to follow the "opt-in" enrollment procedure, the district administration will send a survey to parents/guardians and school staff via e-mail or other communication method with the same study information outlined above (i.e. website link, study information letter, etc.) and the option to opt-in to the study. Upon completion of the survey, the contact information of those parents/guardians and school staff who are willing to participate will be sent directly to the study team. All parents/guardians and who meet criteria (i.e., have a functioning cellular phone that can receive calls and text messages) will be eligible to be randomized to text messaging (TM) or usual care groups. Participants who are randomized to text messaging and that are deemed non-compliant will additionally receive a health navigator (TM + HN) if randomized to that condition.

Procedures for research question #1: *Does text messaging vs. text messaging plus health navigator differentially:*

Interventions to Promote COVID-19 Testing: TMs will be used to screen students and staff and direct families to testing resources. HN will address motivation (both parental and individual for faculty/staff) for testing, logistics and barriers to testing, and support tracking of their own and students' outcomes over time. Test kits provided by the study team will come with a reminder flyer to follow test kit instructions closely and review recommendations by the test kit company for serial testing. Participants who pick up test kits will also receive a flyer with a QR code that links to a form for reporting test outcomes and reminders to complete the study surveys. While we are focused on COVID-19 testing for students and school staff, in the case that the COVID-19 vaccination becomes more relevant or is the priority of the school, we are able to focus our intervention on the vaccine as well.

Text Messages (TMs): We will send HIPAA-compliant bidirectional texts to students' parents or legal guardians (termed "parents" throughout this application) and school staff. Priority groups will be identified in collaboration with partners based on criteria set by the Centers for Disease Control and Prevention (**CDC**), local public health officials, and school priorities. TMs can be tailored based on the closest testing options. A first TM will screen for reported symptoms or COVID-19 exposure to know if the student, staff member or household member should get tested. Individuals who reply "yes" will receive additional TMs with a recommendation to be tested, testing locations/hours/phone and/or information on home testing options, and resources about what to do if they test positive. We will evaluate compliance to the TM intervention. Non-compliant participants will then receive their Phase 2 condition of continued TM or TM+HN to test whether "stepping up" to HN improves outcomes for those not responding to the first-line intervention of TM only.

All participants assigned to TM or TM + HN and respond "yes" will be asked through text message to self-report the number of COVID-19 home test kits taken. Participants will also be asked to self-report through text message the number of (and names of) their enrolled child(ren) that tested positive.

Individuals who reply "no" will be instructed to respond back to the text message at any time should they begin experiencing symptoms or have a new COVID-19 exposure. We will adapt TM targets and content to account for changes such as the status of the pandemic, testing criteria and logistics, and school outbreaks. Our existing TM infrastructure, which can

automatically determine the language in which to send messages, allows us to program and deploy new TMs in a matter of minutes to hours depending on the extent of the adaptations. TMs will be repeated as frequently as needed (e.g., weekly) to continuously screen for COVID-19 testing eligibility, to provide updates, and to assess test completion per parent-report.

Health Navigator (HN):

Some parents and/or school staff members may be reluctant to get tested themselves or to test their children due to knowledge gaps or other concerns or barriers. However, practical advice from navigators can educate and overcome engagement logistics, transportation, and expense barriers. Navigators will be community members who completed case management training through University Neighborhood Partners. Navigators will be taught an empirically validated behavior change approach (Motivation And Problem Solving; **MAPS**). MAPS is based on 20 years of extensive feedback on structure and content from low SES, predominantly minority populations, and has been demonstrated to be effective in increasing enrollment and enhancing and maintaining behavior change. We are using MAPS in multiple studies including in SCALE-UP Utah. MAPS is a holistic, dynamic approach to behavior change that integrates two empirically validated approaches (motivational interviewing and practical problem solving) with demonstrated efficacy for helping patients engage in target behaviors. Importantly, MAPS addresses the social determinants of health, and provides practical advice and connections to services, including addressing testing (and, if relevant, vaccine) concerns (e.g., worries about repercussions of a positive test, infecting family members, quarantining). All navigators will receive ~20 hours of training.

Individuals who receive a TM recommending a COVID-19 test but who did not report completing a test will be contacted by a navigator if they were randomized to that phase 2 condition (as opposed to continued TM). The navigator will address testing (and, if relevant, vaccine) barriers, connect them to a testing site, and discuss implications of a potential positive result. Navigators will provide in-home testing kits to families unable to travel to test sites. We will offer testing to students' and staff members' family members who live in the same household, due to feedback from our school partners that a significant barrier to testing among their families is when other family members, including parents, are also experiencing symptoms. In-school testing will be provided through existing test kits and protocols paid for by UDOH. To manage navigator work queues, we will provide them with access to a dashboard with real-time reports for tracking TM responses that has been implemented through our current RADx-UP project. Navigators will be able to see a list of parents and staff members to call and document outcomes.

Staff:

Contact information for staff who have opted-in (or not opted-out) of the study will be provided to the study team via REDCap. Information provided will include staff name, cell phone number, email address, home address, and role at the school. Schools will also provide the study team with data on the number and timing of missed days of work for enrolled staff which will be used as a secondary measure of intervention effects. The contact information will be used to send text messages informing staff about the study. This message will include

the option to opt-out of participation. Those who do not opt out are randomized. In the first randomization, participants will be randomized to either text messaging or control. The control group assignment consists of typical or usual care for COVID-19 in that school/district, such as following school procedures for state (e.g., Utah Department of Health) recommendations on testing. The second randomization is also participant-level randomization to text messaging + health navigator (HN) coaching versus continued text messaging among participants who are non-compliant by not testing or not responding to testing recommendation follow up.

Randomization:

Randomization of staff participants will consist of two phases, both taking placed upon enrollment in the study. Phase 1 will consist of assigning participates to text messaging or to usual care groups. The Phase 2 randomization will take place among participants in the TM condition. They will be assigned a Phase 2 condition of continued text messages or text messages + health navigator (HN), which they will receive during intervention cycles in which they are evaluated as non-compliant.

Phase 1 Randomization:

Participants included in Phase 1 are those who did not opt-out of the study. Participants eligible for Phase 1 Randomization will either be assigned to **1).** usual care (control, approximately 20% of participants) or **2)**. receive text messages (TM, approximately 80% of participants).

- TM consists of a text message prompt asking if a participant has COVID-19 symptoms or if a participant has been exposed to a person that has tested positive for COVID-19. If a participant responds yes, they will receive a TM prompt for immediate testing and to re-test. Participants will be provided with information on testing options. After 24 hours, the participant will be asked if they tested and what their results are. After 3 days, participants will be prompted to re-test. At the end of the cycle, participants will be asked through text message to state the number of home test kits picked up, number of household members who tested, number of household members who tested positive, as well as the number of (and names of) their enrolled child(ren) that tested positive.
- Usual Care- Participants will only receive public service announcement-type messaging on COVID-19 testing every 3 weeks (e.g., recommendation to obtain COVID-19 testing if exposed or experience symptoms; information on testing options through the school or district).

Phase 2 Randomization:

For participants in the TM condition, the Phase 2 condition will be randomly assigned upon enrollment. Participants will receive their Phase 2 condition if they are non-compliant with the TM intervention. Participants will be evaluated as non-compliant if they had reported symptoms or contact and then stop responding to text messages or respond that they did not

test. Participants will be randomized to **1.)** continued TM or **2.)**continued TM plus health navigator (TM+HN).

- TM will continue to consist of prompts and reminders on COVID-19 testing options. At the end of the cycle, participants will be asked through text message to state the number of home test kits picked up, number of household members who tested, number of household members who tested positive, as well as the number of (and names of) their enrolled child(ren) that tested positive.
- TM+HN consists of continued text messages about COVID-19 testing options with the addition of a brief telephone call from a health navigator (HN). These calls will be conducted using Motivation and Problem Solving (MAPS). MAPS is an empirically validated proactive coaching approach used to address barriers and motivate participants to utilize testing options if they are experiencing COVID-19 symptoms or have been exposed to someone that has tested positive for COVID-19. At the end of the cycle, participants will be asked through text message to state the number of home test kits picked up, number of household members who tested, number of household members who tested positive, as well as the number of (and names of) their enrolled child(ren) that tested positive.

Parents/Students:

Contact information for students' parents/guardians who have opted into the study will be provided via REDCap. Information provided will include the parent/guardian's name, cell phone number, parent/guardian's email, home address, students name, student identification number, and student's school name. Schools will also provide the study team with data on the number of missed school days for enrolled students which will be used as a secondary measure of intervention effects. The contact information will be used to send text messages informing parents/guardians about the study. This message will include the option to opt-out of participation. Those who do not opt out are randomized. In the first randomization, participants will be randomized to either text messaging or control. The control group assignment consists of typical or usual care for COVID-19 in that school/district such as following school procedures for state (e.g., Utah Department of Health) recommendations on testing.. The second randomization is participant-level randomization to text messaging + health navigator (HN) coaching versus continued text messaging among participants who are non-compliant by not testing or not responding to testing recommendation follow up.

Randomization:

Randomization of parent/student participants will consist of two phases, both taking place upon enrollment in the study. Phase 1 will consist of assigning participants to text messaging or to usual care groups. The Phase 2 randomization will take place among participants in the TM condition. They will be assigned a Phase 2 condition of continued text messages (TM) or text messages + health navigator (HN), which they will received during intervention cycles in which they are evaluated as non-compliant.

Phase 1 Randomization:

Participants included in Phase 1 are those who did not opt-out of the study. Participants eligible for Phase 1 Randomization will either be assigned to **1).** usual care (control, approximately 50% of participants) or **2)**. receive text messages (TM, approximately 50% of participants).

- TM consists of a text message prompt asking if a participant has COVID-19 symptoms or if a participant has been exposed to a person that has tested positive for COVID-19. If a participant responds yes, they will receive a TM prompt for immediate testing and to re-test. Participants will be provided with information on testing options for COVID-19. After 24 hours, the participant will be asked if they tested and what their results are. After 3 days, participants will be prompted to re-test. At the end of the cycle, participants will be asked through text message to state the number of home test kits picked up, number of household members who tested, number of household members who tested positive, as well as the number of (and names of) their enrolled child(ren) that tested positive.
- Usual Care- Participants will only receive public service announcement-type messaging on COVID-19 testing every 3 weeks (e.g., recommendation to obtain COVID-19 testing if exposed or experience symptoms; information on testing options through the school or district).

Phase 2 Randomization:

For participants in the TM condition, the Phase 2 condition will be randomly assigned upon enrollment. Participants will receive their Phase 2 condition if they are non-compliant with the TM intervention. Participants will be evaluated as non-compliant if they had reported symptoms or contact and then stop responding to text messages or respond that they did not test. Participants will be randomized to **1.)** continued TM or **2.)** continued TM plus health navigator (TM+HN).

- TM will continue to consist of prompts and reminders on COVID-19 testing options. At the end of the cycle, participants will be asked through text message to state the number of home test kits picked up, number of household members who tested, number of household members who tested positive, as well as the number of (and names of) their enrolled child(ren) that tested positive.
- TM+HN consists of continued text messages about COVID-19 testing options with the addition of a brief telephone call from a health navigator (HN). These calls will be conducted using Motivation and Problem Solving (MAPS). MAPS is an empirically validated proactive coaching approach used to address barriers and motivate participants to utilize testing options if they are experiencing COVID-19 symptoms or have been exposed to someone that has tested positive for COVID-19. At the end of the cycle, participants will be asked through text message to state the number of home test kits picked up, number of household members who tested, number of household members who tested positive, as well as the number of (and names of) their enrolled child(ren) that tested positive.

Procedures for research question #2: *What implementation barriers and facilitators are identified, including by students, parents, schools, and health navigators?*

We will conduct a mixed-methods evaluation to understand implementation effectiveness outcomes as well as characteristics of both schools and students, faculty/staff members and families that may influence intervention effects and implementation outcomes. We will collect ***survey data*** from students, staff members and parents , including items from the NIH RADx-UP Tier 1Common Data Elements (**CDE**). The surveys will assess perceived barriers to participating in SCALE-UP Counts (e.g., lack of interest or need, logistical barriers), facilitators to participating (e.g., receiving ongoing support around COVID-19 testing (and if relevant vaccination), HN), and targets of the intervention (e.g., self-efficacy related to attaining COVID-19 testing). We will collect COVID-19 test results of participants through self-report as well as through results reported to the Ellume testing app. We will also collect implementation predictors from HNs and school nurses, staff, and leaders at each school and district. School staff/leaders and health navigators will complete brief online assessments before and after implementing the interventions. Prior to implementation, school staff and leaders will be surveyed on Implementation Readiness, including priorities, available resources, and access to information using questions adapted from the Organizational Readiness to Change Assessment. We will also assess school setting characteristics (e.g.,leadership engagement, implementation climate) using measures that have been tested for validity and reliability. The post-implementation assessments will measure changes in determinants such as outcome expectations and organizational capabilities targeted by the interventions (e.g., capacity to use information technology systems). Throughout the trial, we will also assess school, district, and local characteristics that are dynamic and influence implementation throughout the project duration (e.g., school/district priorities, policy initiatives, local COVID rates). Adaptation to interventions will be assessed using structured surveys administered to school/district staff and classified using the adaptation framework proposed by Stirman and colleagues.

We will conduct ***stakeholder interviews*** to understand students', participating staff members' and parents' experiences receiving the SCALE-UP Counts interventions and feedback on ways to improve the interventions to better meet their needs and preferences. With school nurses, other school/district staff and leaders, and health navigators, we will conduct interviews to understand their experiences implementing and managing the interventions and to ascertain their recommendations on modifications that are needed to increase the feasibility of implementation, uptake, and effectiveness.

NIH RADx-UP Tier 1 Common Data Elements

NIH RADx-UP Tier 1 Common Data Elements are a common set of questionnaires that NIH has asked investigators (that are funded through the RADx-UP program) to use as part of their studies and to be sent to the Duke Clinical Research Institute (DCRI). Eventually those data can be merged into a single dataset for analysis. Each project is different in terms of the interventions delivered and primary outcomes, so this study does not qualify as a multi-site

study. Individuals are not required to answer the Common Data Element questionnaires to participate in the study.

Participants (staff, parents, and students) who choose to answer the RADx-UP questionnaires will be provided with consent information from the RADx-UP program that details how their information will be used and stored. This consent is provided prior to the completion of every RADx-UP questionnaire participants are asked to complete. Participants will only be asked for identifiable information if they choose to participate in the RADx-UP questionnaires. Common Data Element questions that are shared with the Duke Clinical Research Institute include (but not limited to) personal identifiers such as name, address, contact information, social security number, and date of birth in addition to sociodemographic, housing, and health status questions. Participants are not required to provide this information to complete the questionnaires. A detailed explanation that providing personal identifiers is not required to participate is provided to participants before RADx-UP consent information is asked. If a participant decides to withdraw from the study, only participant data collected to that point would be used.

Participants will be asked to complete the RADx-UP questionnaires at baseline, month 1, month 6, month 9, and month 12. Participants who are enrolled in the intervention but did not complete the baseline survey or other follow up questionnaires (non-responsive participants) may receive a brief survey designed to collect pertinent information related to the study's outcomes (e.g., demographics, COVID-19 testing and vaccine history). This survey consist of a subset of important questions that have already been approved in the current questionnaires. This survey will be sent electronically through REDCap notification and/or through postal mail that includes an insert with a QR code to access the survey. Participants who are no longer enrolled in a participating school will be removed from the intervention but will continue to receive follow up surveys through month 12 from their enrolled school date. These participants will have the opportunity to opt-out of receiving surveys by emailing the study team.

Questionnaires will be sent via text message through REDCap. RADx-UP questionnaire data will be stored on password protected computers. All data that will be transferred outside of the institution to the Duke Clinical Research Institute will be encrypted. Data will be sent to the Duke Clinical Research Institute monthly. This study has a Data Transfer Agreement with Granite School District. The Data Transfer Agreement with RADx-UP/the Duke Clinical Research Institute is pending IRB Approval. Duke Clinical Research Institute will store identifiable information in a secured data base. Duke Clinical Research Institute will use a second secured data base to store and send de-identified data to the NIH.

Procedures for research question #3: *What are the student/family socio-demographic and school characteristic moderators of SCALE-UP Counts effects?*

We will gather data on student, staff member and family socio-demographic characteristics (e.g., race/ethnicity, household income, primary language spoken) and school characteristics (e.g., number of students, percent of students eligible for free and reduced lunch, percent of students who identify as an ethnic minority). These data will lead to a new understanding of

what students and schools benefit most from the interventions and to guide future intervention tailoring to maximize efficacy across settings and for underserved groups.

Procedures performed for research purposes only:

Statistical Methods, Data Analysis and Interpretation

Statistical Analysis and Power for research question #1: We expect to enroll >50% of students and staff members from each of 30 schools (average of >250 students/school). The overall type I error will be split evenly (0.025) for the two co-primary outcomes: percent tested and difference in missed school days. Our primary power assessment is conservatively based on the assumption that students and staff are missing 15% of school days, that the testing rate is 50%, and that the intra-class correlation (**ICC**) is 0.02. The anticipated ICC of 0.02 is consistent with prior school-level association after adjusting for school factors from meta-analyses. Based upon a 2-sample comparison of proportions and using normality approximations, we are 80% powered to detect an improvement of 6.1% fewer missed days of school (missed school days at 8.9% or less) and at least a 9.2% improvement in testing (testing of at least 59.2%) bet. The primary analysis for each primary outcome will entail fitting a linear mixed effects logistic regression model; regressing the outcome upon treatment (TM vs. usual care) and adjusting for fixed effects of school level, percent receiving free/reduced lunch, and percent ethnic minority and for random effects of student, staff member, school, and school nurse.

Analysis for research question #2: We will test whether the quantitative measures of barriers, facilitators, and implementation targets at the student (or staff member) and school level predict testing uptake and missed school days. For each measure, we will fit a mixed effects logistic regression to predict outcomes adjusting for the same fixed and random effects as in Research Question 1. The study is 80% powered to identify student- and staff-level predictors associated with an odds ratio (**OR**) of 1.10 per standard deviation (**SD**) of the predictor for missing school days and an OR of 1.07 per standard deviation of the predictor for testing in univariate analyses or multivariable analyses. For school-level predictors, assuming an ICC for schools of 0.02, the study is 80% powered to identify predictors associated with an OR of 1.27 per SD of the predictor for missed school days and an odds ratio of 1.19 per SD of the predictor for testing, in univariate or multivariable analyses. In secondary analyses, we will use random forests to build a prediction model across quantitative measures at the student and school levels. We will estimate generalizable predictive performance of these models via 10-fold cross-validation and summarize impacts of predictors on outcomes via partial dependency plots. Interview data will be transcribed by the research assistant and subjected to content analysis to identify the primary themes related to barriers and facilitators to intervention receipt, effectiveness, and implementation, and intervention changes recommended. We will

employ recommended methods to integrate the quantitative and qualitative data collected through narrative descriptions and joint displays of the quantitative and qualitative data.

Statistical Analysis and Power for research question #3:

Primary Hypotheses. The 2-phase SMART design provides the opportunity to test multiple hypotheses. Our primary hypotheses (see Significance) address the effects of the interventions on COVID-19 testing rates and missed days of work/school: 1) Is the TM intervention superior to usual care? 2) Among those who are non-compliant to TM, is TM+HN superior to continued TM?

Primary Analyses. Student, staff member and family socio-demographic effect modifiers will be tested using a linear mixed effects logistic regression model; regressing the outcome on treatment (i.e., TM vs. usual care; TM vs. TM+HN) and adjusting for fixed effects of school level, income (qualifies for free/reduced lunch), ethnic minority status, English spoken as primary language, and the interaction between treatment and the aforementioned effect modifier of interest. Random effects will include the student/staff member, school, and school nurse. School level modifiers will be modeled similarly, with school-level characteristics constant over all students within each school. Analyses will account for clustering by school. We will use linear contrasts to estimate main effects of TM vs. use on usual care and (among the participants assigned to TM) the effect of TM+HN vs. continued TM at each post-baseline timepoint.

Power

At the student- and staff- level, assuming 15% school days missed and accounting for unequal allocation of the modifiers, the study is 80% powered to detect a differential effect of 4.7% missed days among students eligible for free/reduced lunches and among ethnic minorities; and the study is 80% powered to detect a differential effect of 7.2% of COVID-19 testing. At the school level, an ICC of 0.02 is assumed and modifiers will be dichotomized at their median. We are 80% powered to detect an effect modifier of 7.5% in days missed school and of 11.9% of COVID-19 testing.