SCALE-UP Utah II: Community-Academic Partnership to Address COVID-19 Text Message Study

NCT05533918

9/5/2024

Supplementary Materials – Study Protocol

Contents

Protocol Paper

Del Fiol G, Orleans B, Kuzmenko TV, Chipman J, Greene T, Martinez A, Wirth J, Meads R, Kaphingst KK, Gibson B, Kawamoto K, King AJ, Siaperas T, Hughes S, Pruhs A, Pariera Dinkins C, Lam CY, Pierce JH, Benson R, Borsato EP, Cornia R, Stevens L, Bradshaw RL, Schlechter CR, Wetter DW. SCALE-UP II: protocol for a pragmatic randomised trial examining population health management interventions to increase the uptake of at-home COVID-19 testing in community health centres. BMJ Open. 2024 Mar 20;14(3):e081455. doi: 10.1136/bmjopen-2023-081455. PMID: 38508633; PMCID: PMC10961568.

https://bmjopen.bmj.com/content/14/3/e081455.long

Institutional Review Board - Study Protocol and Amendments

Date: Thursday, September 5, 2024 3:41:55 PM Print Close

IRB_00150669 **Created:** 1/10/2022 7:14 AM

PI: Guilherme Del Fiol MD, PhD **Submitted:** 3/21/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

1. Study Introduction

1. **Responsible Investigator:**
Guilherme Del Fiol

Email	Training	CoI Date
guilherme.delfiol@utah.edu	1/2/2023 MCG	8/12/2024

a. **Position of the Investigator:**

- (●) **Faculty or** Non-Academic Equivalent
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

2. **Contact Persons for the Responsible Investigator:**

Name	Email	Training
Ray Meads	ray.meads@hci.utah.edu	4/24/2024 MG
Jennyffer Morales	Jennyffer.Morales@hci.utah.edu	7/28/2022 SMCG
Chelsey Schlechter	chelsey.schlechter@hci.utah.edu	9/25/2023 SMCG
David Wetter	david.wetter@hci.utah.edu	1/11/2023 MCG

3. **Guests of the Responsible Investigator:**

Last Name	First Name	E-Mail
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Stevens	Leticia	u6033709@utah.edu

4. **What type of application is being submitted?**
   New Study Application (or Amendment/Continuing Review)

5. **Title Of Study:**
   SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

6. **Study Purposes and Objectives:**

   SCALE-UP II is a state-wide, pragmatic study conducted among 11 Community Health Center (CHC) systems and 38 clinics across Utah. These CHCs serve low socioeconomic status, racially/ethnically diverse, and rural/frontier populations. The long-term objective of SCALE-UP II is to increase the reach, uptake, and sustainability of COVID-19 testing among underserved populations. Through RADx-UP Phase I funding (SCALE-UP Utah), the team has established population health management (PHM) interventions that have been used since Jan 2021 to increase the uptake of COVID-19 testing and vaccination among CHC patients. Interventions are based on a PHM approach that uses widely available technology (i.e. cell phones and text messaging). SCALE-UP II will both build on SCALE-UP Utah PHM interventions and investigate novel interventions (i.e., Conversational Agents and Patient Navigation) that are tailored to address individuals' hesitancy factors and that work at the interplay between vaccination and testing.

   SCALE-UP II builds on long standing partnerships among the University of Utah Clinical and Translational Science Institute (UofU CTSI), Association for Utah Community Health (AUCH), CHCs, and the Utah Department of Health (UDOH). CTSI and SCALE-UP II investigators are leading several COVID-19 initiatives that drive public health response and state government policies in Utah. Thus, the UofU team is uniquely positioned to lead this project.

   SCALE-UP II will implement and evaluate practical, accessible, and scalable PHM interventions to increase COVID-19 testing and vaccine uptake based on the best evidence available, patients' specific barriers and hesitancy factors, and extensive collaboration with CHCs, AUCH, and UDOH:

   a. **Text Messaging (TM):** bidirectional text messaging to connect patients to vaccination or mailed at-home rapid test kits for use as needed.

   b. **Conversational Agent (CA):** automated, scripted and interactive agent used to mimic human interaction to: 1) elicit specific hesitancy factors and barriers to testing; 2) provide individually tailored information to address hesitancy and barriers; and 3) offer a connection to mailed at-home rapid test kits.

   c. **Patient Navigation (PN):** phone call from a community health worker to help address hesitancy and access barriers, and to offer at-home rapid test kits. Two types of PN will be tested: **Request PN** (RPN) will contact only those patients who reply YES to a TM/CA message. No PN will have no contact from a patient navigator.

   Prior to randomization, patients will be triaged into one of two studies based on self-reported ownership of a smart phone with internet access.

   The primary outcome, Testing, captures whether patients actually test with the mailed at-home test kit.

   Secondary outcomes include: ***Time-To-Vaccine*** (time-to-event outcome) as well as several implementation outcomes including ***Reach-Engage Testing*** (proportion of patients that reply to an offer to receive an at-home rapid test kit) and ***Reach-Accept Testing*** (proportion of patients that accept an offer to receive an at-home test kit). A similar set of implementation outcomes will be measured for vaccination (i.e., ***Reach-Engage Vaccine*** *and* ***Reach-Accept Vaccine***).

7. **Is this a multi-site study, where more than one site needs IRB approval?**

● **Yes** ○ No

8. **Background and Introduction:**

Racial/ethnic minority, low socioeconomic status (SES), and rural populations suffer profound health inequities across a wide variety of diseases and conditions, as well as a disproportionate burden of the negative health consequences of the COVID-19 pandemic. As of June 2021, the cumulative COVID case rate in Utah per 100,000 was 10,803 among Whites vs. 17,541 among Latinos. The positivity rate was 14% among Whites vs. 24% among Latinos. Similar disparities persist across the nation regarding vaccination rates between urban vs. rural, high vs. low SES, and White vs. non-White populations. Low vaccination rates leave underserved populations at risk for local outbreaks, and more contagious and severe variants. Thus, interventions targeting these populations at the interplay between testing and vaccination are critical for pandemic control. Not only do underserved populations experience profound health inequities, but there is also a critical digital divide between high and low resource healthcare systems. Low resource settings are far less likely to adopt Health Information Technology approaches, and often do not have the capacity to implement large scale population health management (PHM) efforts utilizing data analytics and automated patient outreach. Community Health Centers (CHCs) are optimal settings for implementing these PHM interventions to increase the uptake of COVID-19 testing and vaccination among underserved populations. Eleven Utah CHC systems are participating in SCALE-UP II. Their 38 primary care clinics serve over 165,000 unique underserved patients annually. Supported by a RADx-UP Phase I grant (SCALE-UP Utah), we have established a flexible text messaging outreach and patient navigation infrastructure with CHCs to increase testing and vaccine uptake. SCALE-UP II will leverage this infrastructure as well as long standing partnerships among the University of Utah Clinical and Translational Science Institute, Association for Utah Community Health, CHCs across the entire state, and the Utah Department of Health.

2. Study Location and Sponsors

1. **Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).**

   Click the appropriate button(s) below to add locations:

	Site Name	Investigators Name	Covered Entity	Sub Sites
View	Association of Utah Community Health	Guilherme Del Fiol	Yes	
View	University of Utah	Guilherme Del Fiol	Yes	
View	Elite Research LLC (Irvine Texas)	Guilherme Del Fiol	Yes	

   a. **Select the lead site. Select N/A if there is no lead site.**
   University of Utah
   ☐ **N/A**

2. **Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study for the sites listed in this application?**
   ● **Yes** ○ No

   a. **Provide the name of the organization providing CIRB/SIRB review:**
   University of Utah

3. **Indicate the source(s) of funding obtained or applied for to support this study.**

	Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type	OrgID
View	DHHS OFFICE OF MINORITY HEALTH	Federal Government				00016197

4. **Does this study have functions assigned to a Contract Research Organization (CRO)?**
   ○ Yes ● **No**

5. **Does this study involve use of the Utah Resource for Genetic and Epidemiologic Research (RGE)?**
   Examples: Utah Population Database (UPDB), Utah Cancer Registry (UCR), All Payers Claims Database (APCD), etc.
   ○ Yes ● **No**

Addition of a Site

1. **Site Name:**
   Association of Utah Community Health

2. **Site Principal Investigator**
   ☑ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   Guilherme Del Fiol

   Email

   guilherme.delfiol@utah.edu

   a. **Position of the Site Principal Investigator**
   Faculty or Non-Academic Equivalent

3. **Site Contact Persons, if different from the Site PI:**
   ☑ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training
Ray Meads	ray.meads@hci.utah.edu	4/24/2024 MG
Jennyffer Morales	Jennyffer.Morales@hci.utah.edu	7/28/2022 SMCG
Chelsey Schlechter	chelsey.schlechter@hci.utah.edu	9/25/2023 SMCG
David Wetter	david.wetter@hci.utah.edu	1/11/2023 MCG

4. **Site Guests:**

Name	Email	Training

There are no items to display

5. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

6. **Select the study procedures that will be conducted at this site:**

   Research observation/intervention with participants

   Other

   Do you have an enrollment goal or anticipated enrollment number for this site?

   ● **Yes**
   ○ No

   Enrollment Number:
   40000

If Other, describe:
AUCH will
1) help to facilitate the transfer of clinical encounter data from participating CHC organization to the University of Utah. A data use agreement has been

developed and signed between the CHCs, AUCH, and the University of Utah for this data sharing.
2) employ the community health workers who will act as patient navigators for the study. Patient navigators work on behalf of the participating CHCs to assist patients in accessing COVID tests.

7. **Add any additional sites that are part of this performance group**
   There are no items to display

Addition of a Site

1. **Site Name:**
   University of Utah

2. **Site Principal Investigator**
   ☑ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   Guilherme Del Fiol

Email	Training	CoI Date
guilherme.delfiol@utah.edu	1/2/2023 MCG	8/12/2024

   a. **Position of the Site Principal Investigator**
   Faculty or Non-Academic Equivalent

   b. **Will the Site PI consent participants?** ○ Yes ● **No**

3. **Site Contact Persons, if different from the Site PI:**
   ☑ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training
Ray Meads	ray.meads@hci.utah.edu	4/24/2024 MG
Jennyffer Morales	Jennyffer.Morales@hci.utah.edu	7/28/2022 SMCG
Chelsey Schlechter	chelsey.schlechter@hci.utah.edu	9/25/2023 SMCG
David Wetter	david.wetter@hci.utah.edu	1/11/2023 MCG

4. **Site Staff and Sub-Investigators**

Name	Email	Training	Obtaining Consent	CoI Date
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Emerson Borsato	emerson.borsato@utah.edu	10/10/2023 SMG	☐	8/6/2024
Rick Bradshaw	rick.bradshaw@utah.edu	8/8/2024 MCG	☐	8/26/2024
Jonathan Chipman	jonathan.chipman@hci.utah.edu	8/1/2022 SMCG	☐	8/19/2024
Ryan Cornia	ryan.cornia@utah.edu	8/18/2023 MCG	☐	8/23/2024
Bryan Gibson	Bryan.Gibson@utah.edu	5/11/2022 MCG	☐	8/6/2024
Rachel Hess	rachel.hess@hsc.utah.edu	12/16/2021 SMCG	☐	8/12/2024

Name	Email	Training	Obtaining Consent	CoI Date
Kimberly Kaphingst	kim.kaphingst@hci.utah.edu	4/25/2022 SMCG	☐	8/6/2024
Kensaku Kawamoto	kensaku.kawamoto@utah.edu	1/19/2024 MCG	☐	6/28/2024
Tatyana Kuzmenko	tatyana.kuzmenko@utah.edu	4/19/2022 MCG	☐	8/6/2024
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Jennyffer Morales	Jennyffer.Morales@hci.utah.edu	7/28/2022 SMCG	☐	8/16/2024
Brian Orleans	brian.orleans@hsc.utah.edu	11/2/2022 MCG	☐	1/19/2024
Joni Pierce	joni.pierce@utah.edu	6/21/2023 MG	☐	4/12/2024
Leticia Stevens	u6033709@utah.edu	11/6/2023 MCG	☐	8/1/2024
Ellen Wight	ellen.m.wight@gmail.com	7/21/2023 MCG	☐	8/26/2024

5. **Site Guests:**

Name	Email	Training
Maria Guadarrama	maria.guadarrama@hci.utah.edu	4/14/2022 SMCG

6. **Select HIPAA coverage for this study:**
Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

7. **Select the study procedures that will be conducted at this site:**

Recruitment

Consent/Enrollment

Data collection

Data analysis

Do you have an enrollment goal or anticipated enrollment number for this site?

● **Yes**
○ No

Enrollment Number:
26000

8. **Select the University of Utah department responsible for this research:**
HUNTSMAN CANCER INSTITUTE

9. **Add any additional sites that are part of this performance group**
There are no items to display

Addition of a Site

1. **Site Name:**
   Elite Research LLC (Irvine Texas)

2. **Site Principal Investigator**
   ☑ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   Guilherme Del Fiol

   Email

   guilherme.delfiol@utah.edu

   a. **Position of the Site Principal Investigator**
   Faculty or Non-Academic Equivalent

3. **Site Contact Persons, if different from the Site PI:**
   ☑ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training
Ray Meads	ray.meads@hci.utah.edu	4/24/2024 MG
Jennyffer Morales	Jennyffer.Morales@hci.utah.edu	7/28/2022 SMCG
Chelsey Schlechter	chelsey.schlechter@hci.utah.edu	9/25/2023 SMCG
David Wetter	david.wetter@hci.utah.edu	1/11/2023 MCG

4. **Site Guests:**

Name	Email	Training

There are no items to display

5. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

6. **Select the study procedures that will be conducted at this site:**

   Consent/Enrollment

   Data collection

   Do you have an enrollment goal or anticipated enrollment number for this site?

   ● **Yes**
   ○ No

   Enrollment Number:
   43325

7. **Add any additional sites that are part of this performance group**
   There are no items to display

Sponsor Information

a. Are you receiving award or contract management for the sponsored funds through the University of Utah Office of Sponsored Projects?

● **Yes** ○ No

If yes, select the associated OSP Proposal ID/DSS through eAward to link it to the ERICA system.

You must have a fully approved Proposal ID/DSS number through eProposal which will show up in eAward after OSP has integrated the ID. To access the eAward application, use the instructions on the OSP website.

Link to a Proposal ID/DSS through eAward

Proposal ID/DSS: 10062178
PI: DEL FIOL,GUILHERME
Sponsor: DHHS OFFICE OF MINORITY HEALTH
Prime Sponsor:
Department:
Short Title: U01, SCALE-UP 2
Sponsor Award Number: 5U01MD017421-02
Type: Federal Government
Award Start Date: 1/1/2022
Award End Date: 11/30/2024
Prime Sponsor Type:

IRB_00150669 **Created:** 1/10/2022 7:14 AM

PI: Guilherme Del Fiol MD, PhD **Submitted:** 3/21/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

3. Participants

1. Ages of Participants:

Less than 7 years old	(Parental permission form needed)
7 to 17 years old	(Parental permission and assent form needed)
18 and older	(Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):
all ages

3. Indicate any vulnerable participant groups (other than children) included:

None

If "Other", please specify:

If "None" and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
◯ Yes ◯ No

4. Number of participants to be included and/or enrolled in this entire study, across all study locations: 43,325

5. Characteristics of Participants/Inclusion Criteria:

To be eligible, patients must have a working cellphone, have their phone number listed in their existing electronic medical record at their participating clinic, and speak English or Spanish.

6. Participant Exclusion Criteria:

N/A

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?

◯ Yes ● **No**

Vulnerable Populations

Justification Requirements for the Inclusion of Vulnerable Populations

1. **How does the nature of the research require or justify using the proposed subject population?**
   Children aged 17 and younger are susceptible to contracting and transmitting the COVID-19 virus and thus, are included in our broad scope of participants who would benefit from an intervention to increase testing rates among low socioeconomic status, racially/ethnically diverse, and rural/frontier populations. Children aged 17 and younger will not directly receive any study contact IE: text messages, links to conversational agents, patient navigation, or surveys. Their data is included to ensure access to COVID 19 at-home testing, if their parent chooses to request one for them.
2. **Would it be possible to conduct the study with other, less vulnerable subjects?**
   ● **Yes** ○ No

   If yes, justify the inclusion of vulnerable subjects:
   However, the exclusion of children would greatly diminish the generalizability that the study results would have to a proportion of individuals, children aged 17 and younger, who are at risk for the transmission of COVID-19.
3. **Is this population being included primarily for the convenience of the researcher?**
   ○ Yes ● **No**

   If yes, explain:

4. Study Information

1. **Design of Study (select all that apply):**

   ☑ **Non-Experimental and/or Descriptive Research Design:**

   Secondary/Archival Data Analysis or Retrospective Chart Review
   Survey/Questionnaire Research

   ☑ **Experimental and/or Interventional Research Design:**

   Randomized Trial

   ☑ **Development of a research resource (repositories, databases, etc.)**

   There are no items to display

   ☐ **Other**

2. **Does your study involve the use of any placebo?**
   ○ Yes ● **No**

3. **Length of entire study, from initiation through closeout:**
   2 years

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**

   Written or electronic record review

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   The patients that are recruited for this study will be identified via an EHR system within participant's clinics. The study team will work with an IT team to pull pertinent information from patient records via a population health management tool. The data will be transferred through AUCH to the U of U study team. The study team will then use that data to determine the cohort for the study. The data will include patient contact information which will be used to contact patients, via text message and/ conversational agent, about COVID-19 testing and/or vaccine eligibility. The text messages will appear to originate from the patient's primary clinic. CHC patients are routinely contacted by their CHC via phone calls and text messages, therefore the text messages are not beyond the scope of routine care and correspondence.

5. **How will consent be obtained?**

   Informed Consent Process (with or without a document)

   Waiver or Alteration of Informed Consent

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

SCALE-UP Utah II is composed of two experimental studies, which allow participants access to COVID-19 testing and/or vaccine resources via technology-based interactive platforms. Participant cohorts will be selected from the electronic medical records pulled from the participating community health centers. Minors (under 18) will be included in the data pull, however people under the age of 18 will not be included in any of the following interventions (IE: text messages, conversational agents, patient navigation, or surveys). Their information is included to allow for parents to request COVID tests for their children. Children will not be contacted by the study for any reason. Due to this lack of any direct contact, the study is utilizing an "assent waiver" for children under the age of 18.

Participants will be triaged into one of the two designs based on self-reported smart phone access. Individuals who report using a smart phone will be placed in the Conversation Agent (CA) study /Text Message (TM) study and subsequently be randomized between either a CA or TM arm. Individuals who report they do not use a smart phone or do not respond within a certain timeframe, will be placed in the Text Message (TM) Only study. Both studies will stratify the population between two different levels of patient navigation (PN). Patient Navigation will consist of a patient navigator calling participants who request a call from a PN. Patients will be randomly assigned to either No PN or Request PN (RPN).

The CA study will utilize a customized conversational agent platform, which is HIPPA compliant to provide patients with an interactive, dynamic experience to reach COVID-19 testing and/or vaccine resources.

The TM Only study will use a bi-directional text messaging platform to send patients messages about COVID testing and/or vaccination. The message response logic is based on the patient's responses to the messages. The answer options for patients will be simple and allow patients to STOP the intervention at any time.

Within the Conversation Agent (CA) study and the Text Message Only (TM) study, patients will be randomized to one of two patient navigation arms: No PN or Request PN (RPN). Patients randomized to No PN, will not be connected by a patient navigator. Patients randomized to RPN will only be called if they request a call by replying PERSON to a text message.

In RPN patient navigators will assist patients address barriers in engaging in COVID-19 testing and/or vaccination.

Population Health Management Interventions:

SCALE-UP Utah II will build on the standing partnerships among the University of Utah Clinical and Translational Science Institute, Association for Utah Community Health (AUCH), Community Health Centers across the state, and the Utah Department of Health (UDOH); and will leverage infrastructure enabled in SCALE UP Utah I. Hence, we have agile infrastructure, collaborations, and processes that are "shovel ready" to support novel, practical and scalable PHM interventions to increase COVID-19 testing and vaccination among Utah CHC patients.

The study team's primary outcome, Testing, captures whether patients complete at-home tests that were requested through the study.

The secondary outcomes, Time-To-Vaccine (time-to-event outcome) as well as several implementation outcomes including Reach-Engage Testing (proportion of patients that reply to an offer to receive an at-home rapid test kit) and Reach-Accept Testing (proportion of patients that accept an offer to receive an at-home test kit). A similar set of implementation outcomes will be measured for vaccination (i.e., Reach-Engage Vaccine and Reach-Accept Vaccine).

This experimental aims are:

a. Conducting a 2 (TM vs. CA) X 2 (No PN vs. RPN) factorial design assessing intervention effects on testing outcome. The study team hypothesizes a main effect for CA being more effective than TM Only, and a main effect for PN, comparing RPN vs. No PN (RPN > No PN).

b. Conducting a 2 arm (No PN vs. RPN) trial among a subset of participants who receive only text messaging (no chatbot). The study team hypothesizes a main effect for PN, comparing RPN vs. No PN (RPN > No PN).

c. Examining factors associated with at-home testing and/or vaccination uptake over the life of the study. The study team will assess predictors of outcomes and moderators of intervention effects, such as characteristics of patients and contextual factors related to the status of the pandemic.

Text Message Only Study

Overview:

The Text Message Only Study is comprised of participants who either do not answer the original screener question regarding smart phone use or answer that they do not use a smart phone.

Patients in the Text Message Only design will be randomized between two different conditions; TM only (no PN) and TM+ RPN. Patients in the TM only condition will receive HIPAA-compliant bidirectional text messages. Texts will include a brief message regarding COVID-19 testing and/or vaccination information. Patients who reply "yes" will

receive additional messages with a recommendation to be tested in-clinic or at home and/or vaccinated. Additionally, they will receive in-clinic testing and/or vaccination locations/hours/phone and/or patient will be able to request an at-home testing kit, based on participating clinic involvement. At-home test kits are FDA approved, free of cost to the participant, and sent on behalf of the participants' clinic. Patients who reply “no” may receive a text with the clinic phone number and a note to call if anything changes. Patients in this No PN condition will not receive any PN phone calls.

Patients in the TM+RPN condition will receive the same text messages and testing/vaccination options as the patients in the TM only condition. Patients randomized to TM+RPN will be given the option to request a call by replying PERSON to a text message.

Conversational Agent / Text Message Study

Overview:

The Conversational Agent/Text Message Study is comprised of patients who answer the original screener question regarding smart phone use affirmatively, meaning that they do use a smart phone.

Patients in the Conversational Agent/ Text Message Study will be randomized into two different arms; 1) Conversational Agent (CA) and 2) Text Message No Conversational Agent (TM- No CA).

The TM- No CA group will receive HIPAA-compliant bidirectional text messages, just like the message sent to the participants in the TM Only Study. Patients will be randomized between two different conditions: TM - No CA (no PN) and TM+RPN.

Patients in the TM- No CA only (no PN) condition will receive HIPAA-compliant bidirectional text messages. Texts will include a brief message regarding COVID-19 testing and/or vaccination information. Patients who reply “yes” will receive additional messages with a recommendation to be tested in-clinic or at home and/or vaccinated. Additionally, they will receive in-clinic testing and/or vaccination locations/hours/phone and/or patient will be able to request an at-home testing kit, based on participating clinic involvement. At-home test kits are FDA approved, free of cost to the participant, and sent on behalf of the participants' clinic. Patients who reply “no” may receive a text with the clinic phone number and a note to call if anything changes. Patients in this condition will not receive any patient navigation phone calls.

Patients in the TM+RPN condition will receive the same text messages and testing/vaccination options as the patients in the TM only condition. Patients randomized to TM+RPN will be given the option to request a call by replying PERSON to a text message.

Patients assigned to the CA arm of the CA study will receive a controlled and automated, interactive agent to aid in identifying and providing COVID-19 testing and/or vaccine information, and provide patients with the ability to order at-home tests to be delivered to their home. In this arm patients will be randomized between two different study conditions; CA Only (no PN) or CA+RPN.

Patients in the CA only condition will receive a HIPAA-compliant option to connect with an interactive agent. Information provided will include a brief message regarding COVID-19 testing and/or vaccination information that can be provided to the patient, such as at-home testing kits. Patient in this arm will not receive any phone calls from patient navigators.

Patients in the CA+RPN condition will receive the same interactive agent option that provides testing/vaccination resources and connections. Patients randomized to CA+RPN will be given the option to request a call by replying PERSON in the chat bot.

Step One:

Primary Data Extraction

To identify the cohorts for the PHM intervention, a subset of EHR data will be manually extracted from the CHCs. The EHR reports will contain all patients 18 years or older seen at each of the CHCs in the last 3 years. Subsequent reports will be obtained, at most weekly, including all encounters in the previous week. Data fields will include risk factors such as age, gender, body mass index, encounter diagnoses for medical co-morbidities, patient demographics (e.g., zip code, insurance status, preferred language, race/ethnicity, parental/family status); as well as cellphone number for text messaging and patient navigation. Participating CHCs will share these clinical encounter reports with AUCH, who will then securely transfer the data to the University of Utah study team. The data will then be hosted at the U of U Center for High Performance Computing.

The primary data extraction and use of data is designed to be covered by a waiver of informed consent, as approved by the IRB.

Step Two:

Secondary Data Inclusion:

A secondary data source for this project will be vaccination records from the Utah Statewide Immunization Information Systems (USIIS). USIIS is a voluntary collection system. Individuals may opt-out of sharing their vaccine records with USIIS at any time. In accordance with Utah Code 26-3-7(3) Utah Department of Health allows researchers to request access to USIIS data for "valid research." This data sharing will be covered through a data use agreement between the University of Utah and Utah Department of Health.

The process for this matched collection is as follows... Participating Community Health Centers will send USIIS a list of patients participating in SCALE UP. These records will include patient identifiers such as name, DOB, address, primary clinic, and MRN. Community Health Centers routinely send patient information to USIIS. This transfer of data is routine clinical practice and covered through DUAs between the clinics and USIIS. USIIS will then perform a match between the lists from the CHCs and their vaccination records. USIIS will then send the University of Utah the matched data sets. These records will include name, DOB, address, primary clinic, MRN, and COVID-19 vaccination administration details. This transfer will take place over a HIPPA compliant platform and be stored securely at the Center for High Performance Computing. These data matches and transfer from USIIS to the SCALE UP team will occur as frequently as every two weeks to ensure that researchers are using the most up to date vaccination records for patients.

Step Three:

Cohort Selection & Randomization

Once the data are securely housed at the Center for High Performance Computing, the study team will determine cohort building criteria. Cohort selection will be based on EHR data considering factors such as age, race/ethnicity, language, relevant medical comorbidities, and residence in hotspot areas. These selection criteria are consistent with recommendations from UDOH and the CDC.

Once the cohort selection criteria are determined, patients are assigned between the two study designs based on their answer to the smart phone screener question. Once triaged to each study, patients are then randomized between the various arms and conditions within each study.

Step Four:

Implementation

Text Messaging Only Study

Patients assigned to the Text Message study will receive HIPPA-compliant bidirectional texts, which is a communication method routinely used by the CHCs, to patients in high-risk cohorts. Text messages will be designed by the research team and sent using a HIPPA compliant text messaging service. The text messaging service will retrieve the patient cohort from the study database to send the TMs to the patients. The text messages will appear to the patients as having originated from their CHC. As part of their general CHC care, patients have agreed to be contacted by their CHC and text message communication is one of those established contact methods. Text messages will be repeated either every 10 days or 30 days, to continuously screen for COVID-19 testing and vaccination eligibility and to provide updates. Every text message will include the option to reply STOP to cease receiving text messages at any time.

Text messages will include a brief message regarding COVID-19 testing and/or vaccine information. The content of the text messages will be the same across the three different patient navigation conditions.

Patients in the TM only (No PN) condition who reply “yes” will receive additional messages with a recommendation to be tested, testing locations/hours/phone, and/or have the ability to request a free at-home test be sent to their home on behalf of their CHC.

Patients assigned to TM+RPN who reply “yes” will receive a call from a Patient Navigator. Patient Navigators will talk to patients about free at-home testing and patients will have the option to request a free at-home test sent to the patient on behalf of their CHC. The duration of patient navigator involvement will vary from patient to patient, depending on the complexity of the case. If a patient declines PN they will no longer receive PN intervention.

Conversational Agent/Text Message Study

Patients assigned to the CA/TM Study will be randomized between receiving access to a Conversational Agent (CA) or the same bi-directional text message intervention as the Text Message Study (TM). Patients in both groups (CA and TM) will then be randomized between two arms of patient navigation, No PN or RPN. Therefore, in the CA/TM study, there are four different groups of participants: CA only, CA+RPN, TM only, and TM+RPN. The two arms of patient navigation are the same as in the TM Only Study.

To avoid duplication and potential inconsistencies, patients who test positive for COVID-19 will be managed based on current procedures already offered by UDOH, AUCH, and CHCs. AUCH and UDOH currently have multiple initiatives

for helping patients who test positive with additional resources, including a community health worker program to support COVID-19 positive and/or high-risk patients in quarantine. Patients that request free at-home testing will not be required to share their results with their CHC but will receive health education in case they test positive by their Patient Navigator.

Patient Surveys:

All patients that request an at-home COVID-19 testing kit, as well as a matched sample of those who do not request a test, will be asked to complete an online or phone survey to assess use of COVID-19 testing and to collect the RADx-UP Tier 1 Common Data Elements (CDEs). Surveys will first be offered online and when not completed; a follow-up phone will occur to aid in the survey completion. The survey will be offered 3 months after a participant is eligible to receive an at-home test. The initial survey offer will include a pre-survey cash incentive as well as a letter of consent prior to starting the survey. If a patient does not consent, they will not be asked to complete the survey. Participants who complete the survey will be provided a gift card as an incentive. Only patients 18 and older will be asked to participate in surveys. Parents who request COVID tests for their children (under the age of 18) may be asked questions about the outcomes of those tests in the surveys. Because children are not directly contacted or provided with interventions, this study will be utilizing a "waiver of assent" for children under the age of 18. An approved University of Utah survey vendor will administer this survey.

The incentives for the survey are structured such that an individual may receive either $2, $5, or $10 as a pre-survey incentive and either $20, $25, $28, or $30 as a post-survey incentive. There is a scale of incentives so that the study team may analyze the effect of dynamic survey incentives as an sub-outcome of the study.

Data Transfer:

Throughout the course of the study, on a quarterly basis, the study team will send identifiable patient data and study outcomes to project's sponsor, The National Institutes of Health. The identifiable information being transferred will include the CDE portion of the survey. This process will be detailed and approved through data transfer agreements involving the community health centers, the Association for Utah Community Health, The University of Utah Office of Sponsored Projects, The University of Utah IRB, and Duke University, which is housing the data for the National Institutes of Health.

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ● **Yes** ○ No

   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ● **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   We will conduct two randomized clinical trials: RCT 1 includes participants who affirm they have a smart phone and RCT 2 includes all other participants. We will perform two categories of statistical analyses: 1) Comparing the main effects of TM vs. CA (RCT 1), main effects of RPN vs. no PN (RCT 1 and 2 combined), interaction effects (RCT 1), and follow-up pairwise comparisons of the study arms (RCT 1 and 2); and 2) Evaluating predictors of outcomes and moderators of intervention effects (RCT 1 and 2).

   Primary Analyses of *Testing* for TM vs. CA and no PN vs. RPN. Alpha will be set at 0.0167 to maintain a family-wise error rate of 0.05 across the three primary hypotheses comparing treatment arms. We will apply generalized estimating equations to implement a repeated measures logistic regression to relate the probability of receiving a COVID-19 test within a shorter time frame to the randomized treatment group. Robust sandwich variance estimates will be utilized to account for dependencies between potential repeated observations on each subject (i.e. several potential time-intervals post-randomization where patients might test).

   Predictors of outcomes and moderators of intervention effects. Multilevel generalized linear mixed models will investigate the association between patient, provider, and CHC/clinic level predictor variables with implementation outcomes for each intervention. We will test for patient characteristics and contextual pandemic factors as outcome moderators by fitting an interaction term of each moderator by intervention.

   Statistical Power. The participating CHCs have 43,325 patients with a clinical encounter in the past three years. In SCALE-UP Utah, 15% of patients have opted out of receiving text messages and will not be included in SCALE UP II. Based on data from SCALE-UP Utah and prior research, we anticipate ~20% opt outs, leaving a total of ~29,500

patients for randomization to the six study arms. We have satisfactory power for detecting feasible CA vs TM; and RPN vs No PN differences on our primary outcome of *Recurrent-Testing*.

Created: 1/10/2022 7:14 AM

PI: Guilherme Del Fiol MD, PhD

Submitted: 3/21/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

Request for Waiver or Alteration of Consent

* Requested Waivers

	Date Created	Type of Request	Purpose of Waiver Request
View	2/25/2022	Waiver of Informed Consent	The purpose of this waiver is to review EHR patient data at participating CHCs and linked USIIS vaccination data, using that data to establish cohort selection for research intervention, and randomizing selected patients to research interventions without the patient's consent.
View	2/25/2022	Waiver of Informed Consent	The purpose of this waiver is for the use of EHR and USIIS data post-intervention implementation to analyze which patients, randomized to each intervention, were ultimately tested and/or vaccinated for COVID-19.

Request for Waiver or Alteration of Consent

1. **Purpose of the Waiver Request:**
   The purpose of this waiver is to review EHR patient data at participating CHCs and linked USIIS vaccination data, using that data to establish cohort selection for research intervention, and randomizing selected patients to research interventions without the patient's consent.

2. **Type of Request:**
   Waiver of Informed Consent

3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).**
   We plan to keep links to patient's names, date of birth, contact information, address, demographic information, insurance status, tobacco use status, medical record number (MRN), encounter diagnoses, COVID-19 lab test orders, COVID-19 lab test results, COVID-19 vaccine orders, guarantor status, communication preferences, and translator services required.

4. **Explain why the research could not be practicably conducted without using identifiable information. Examples of such explanation could include the following:**
   Identifiable information is needed to identify eligible patients for randomization, and to contact the eligible patients for conversational agent, text messaging, and patient navigation.

5. **Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":**
   Due to the scope and design of the study, our research team would be unable to contact patients and collect consent within the timeframe necessary to impact COVID-19 screening, testing, and vaccination.
   If informed consent procedures were required for this project, all patients who had visited a CHC in the past three years (over 165,000 patients) would need to be contacted and met with to obtain consent prior to the start of the study. This effort would take several years and is therefore impossible to complete within the timeframe of the project.
   Given that the study intervention is consistent with the CHCs standard of care and outcomes will be collected from the EHR, informed consent could be reasonable waived thus making the current study and its reach to underserved populations possible.

6. **Explain why the research and privacy risk of the research are no more than *minimal:***
   The research is no more than minimal risk as neither the text messages nor patient navigation are sensitive in nature, and CHCs frequently utilize similar methods in their normal and routine care of patients. For example, Community Health Center clinics frequently send text messages to their patients for appointment reminders, and use patient navigators or health coaches as part of routine care and treatment engagement. Furthermore, extensive procedures are in place to ensure the privacy of patients will be protected and their data will remain confidential. Data use agreements to obtain patient contact information will be put into place between each CHC

Organization, the Association of Utah Community Health (AUCH), and the University of Utah prior to beginning the relevant study procedures.

7. **Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the *subjects:***
   The information collected as part of this study will be used and stored using procedures designed to safeguard the patients' privacy and confidentiality. The randomization to evidence-based treatment engagement strategies (i.e., text messaging, conversational agents, and coaching calls) will not change the clinical care the patient receives at the CHC clinic. Participants not randomized to receive conversational agent, text messaging and patient navigation will continue to be advised to monitor and test of COVID-19 symptoms in typical practice at visits to CHC clinic, protecting their welfare for treatment engagement. Participants randomized to receive text messages, conversational agents, or patient navigation have the option of not answering the text messages or the patient navigation calls if they choose, and are able to opt-out of future messages and future calls, therefore giving them the right to withdraw from participation in text messages, conversational agent, and patient navigation at any time during the study. As such, a reasonable person who is in a participant's position, whether the patient is randomized to receive or not receive text messages, conversational agent, or patient navigation, would not consider the waiver as adversely affecting their rights and welfare.

8. **Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information *after* they have participated in the study, or indicate *"Not applicable":***
   Not applicable. Providing participants pertinent information after participation is not appropriate as the results would have no effect on the individuals.

Request for Waiver or Alteration of Consent

1. **Purpose of the Waiver Request:**
   The purpose of this waiver is for the use of EHR and USIIS data post-intervention implementation to analyze which patients, randomized to each intervention, were ultimately tested and/or vaccinated for COVID-19.

2. **Type of Request:**
   Waiver of Informed Consent

3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).**
   We plan to keep links to patient's names, date of birth, contact information, address, demographic information, insurance status, tobacco use status, medical record number (MRN), encounter diagnoses, COVID-19 lab test orders, COVID-19 lab test results, COVID-19 vaccination orders, and COVID-19 vaccination outcomes, guarantor status, communication preferences, and translator services required.

4. **Explain why the research could not be practicably conducted without using identifiable information. Examples of such explanation could include the following:**
   Identifiable information is needed to link patients with COVID-19 testing options (including at-home tests) and vaccination outcomes.

5. **Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":**
   The partnering CHCs see over 165,000 patients each year. It would be impossible to contact every patient who had visited a CHC in the past three years to authorize use of their EHR data. It is estimated that approximately 118,000 patients could be part of this intervention. Requesting that the participating CHCs obtain informed consent from all of these patients would place unrealistic burden on the CHCs and make it impossible for them to participate in the research. Additionally, it would be impossible for the study team to contact all of these participants, who will be located across the state of Utah, and obtain consent in the time necessary for meaningful use of COVID-19 test results. If consent to use test result data were necessary, it would not be feasible to conduct this research.

6. **Explain why the research and privacy risk of the research are no more than *minimal:***
   The research is no more than minimal risk as the results of COVID-19 screening, testing, and vaccination is not sensitive information and will not be used to impact the lives of the patients. Furthermore, extensive procedures are in place to ensure the privacy of patients will be protected and their data will remain confidential. Data use agreements to obtain patient contact information will be put into place between each CHC Organization, the Association of Utah Community Health (AUCH), and the University of Utah prior to beginning the relevant study procedures.

7. **Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the *subjects:***

The information collected as part of this study will be used and stored using procedures designed to safeguard the patients' privacy and confidentiality. Additionally, the information collected will not further impact the care the individual can or will receive at their CHC. A reasonable person who is in the participants position would not consider the waiver as adversely affecting their rights because the data are not being used to directly impact their care.

8. **Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information *after* they have participated in the study, or indicate *"Not applicable":***
   Not applicable. Providing participants pertinent information after participation is not appropriate as the results would have no effect on the individuals.

Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Study Location and Sponsors Page):**
   There are no items to display

   List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).
   Online Consent:
   There are no study members involved in the consent process for participants who complete their consent forms online

   Phone Consent:
   The approved University of Utah survey vendor will obtain consent for the 3-month follow up participant survey for those who choose to complete the survey over the phone.

2. **Describe the location(s) where consent will be obtained.**
   Online Consent:
   Online consent form links will be sent to participants via text message to be completed online.

   Phone Consent:
   The approved University of Utah survey vendor will obtain consent for the 3-month follow-up participant survey. Patient consent to complete the survey will be obtained using a consent cover letter over the phone.

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**
   3-month follow-up survey:

   Participants who request an at-home test throughout the course of the project as well as a matched sample of those who do not request a test, will be asked to complete a survey 3 months after they request their first at-home COVID test. This survey will be administered by an approved University of Utah survey vendor
   Patients will be invited to complete the 3-month survey through mail invites and/or text invites and/or phone contact. The approved University of Utah survey vendor will complete the consent and survey over the phone for participants who choose to complete the survey over the phone.
   There is no waiting period between the consent process and obtaining consent from a participant.
   Only participants who are 18 and older will be asked to complete the survey. Parents who request a test for their child may be asked questions regarding the outcomes of those tests, however the children will not receive any direct contact from the study. Therefore, this study is requesting the use of a "waiver of assent."

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
   All patients will be given the option to participate or not participate in the survey. Patients will be able to ask questions prior to making a decision and are able to decline any portion of the study at any time. Due to the low risk nature of the study and the ability of patients to decline any portion of study at any time, the possibility of coercion or undue influence is minimized significantly.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
   All patients will be given the option to participate or not participate in the survey. Patients will be able to ask questions prior to making a decision. Contact information for these question will be provided on the consent letter and on the survey.

6. **Will a legally authorized representative (LAR) be used?**
   ○ Yes ● **No**

7. **Will a language other than English be used to obtain consent?**
   ● **Yes** ○ No

   a. **Please indicate which form will be used:**

      A translated consent document.

   b. **Describe whether translation services will be used for the consent process and how the consent process will be conducted?**

      The consent document and survey will be administered in Spanish for participants who have Spanish listed as their primary language in their electronic medical record. There will not be any translation services used during the consent or survey administration.

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**
   ● **Yes** ○ No

   If yes, complete the following:

   a. **Explain why the waiver of consent documentation is being requested.**

      We are requesting the waiver of documentation for the patient survey. We will be using a consent cover letter for this data collection and will explain to participants that completed/returned surveys act as the participants consent to participating in the research study.
      As part of the survey, an approved University of Utah vendor will obtain consent for the patient to complete the survey. Patient consent to complete the survey will be obtained using a consent cover letter either online or over the phone. Online they will be able to review the approved consent letter and at any time stop the process if they do no wish to continue. A written consent script will be used to aid patients in completing the survey over the phone when contacted by the approved University of Utah vendor. This will allow the survey research firm to consent to participants over the phone for the survey. This allows participants access to the consent information in a conversation format and lessen the burden on participants that are contacted over the phone by providing information in an easy to understand but comprehensive manner. We will provide all participants with the option of requesting a copy of the consent letter. They also may print it themselves if they are completing the survey online.

   b. **Justification for the waiver is one of the following:**

      The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:

   - The research intervention is conducted in a private place
   - The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

   Other or additional details (specify):

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:

   - Storing research data on password protected computers or in locked cabinets or offices
   - All data that will be transferred or transported outside of the institution will be encrypted
   - A Certificate of Confidentiality (from the NIH) will be used

   Other or additional details (specify):

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

   ○ Yes ● **No**

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:

   - Periodic review and confirmation of participant eligibility
   - Periodic review of the transfer/transcription of data from the original source to the research record
   - Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

   Other additional details (specify):

5. **Who will be the primary monitor of the study data and documentation?**

   Select all that apply:

   - Principal Investigator
   - Study Coordinator or Research Nurse

Other or additional details (specify):

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
   Research staff will regularly (weekly) meet with the PI to discuss concerns, issues, and study progress.

IRB_00150669
6. Risks and Benefits

6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

We foresee minimal risks or discomforts to participants. As per usual clinical visits and documentation, patients may feel some distress when approached regarding COVID-19 testing and vaccination given the pandemic's social and economic toll. Additionally, as with the collection of any identifiable information, there is minimal risk that confidentiality could be breached. However, we have several safeguards in place to prevent this from happening.

2. Describe the potential benefits to society AND to participants (do not include compensation):

Because the risks are unlikely and minimal to individuals, we feel that they are reasonable in relation to the patient care that participants will gain regarding COVID-19 testing and vaccination. Connection to testing and vaccination sites and COVID-19 resources may be a benefit to patients who may not have received the information without this program in place. Additionally, benefits to society include the effectiveness outcomes of this clinical approach to managing the COVID-19 pandemic that could in turn be used nationally to reach under served populations disproportionately impacted by the virus outbreak.

Additionally, there is the potential that there will be no direct benefit to participants of this study.

3. Are there any costs to the participants from participation in research?

○ Yes ● **No**

If yes, specify:

4. Is there any compensation to the participants?

● **Yes** ○ No

a. If yes, answer the following:

Specify overall amount:

This project is using a dynamic incentive structure to test the effectiveness of varying levels of pre- and post-survey compensation.
Patients will receive one of the following amounts for a pre-survey incentive [$0,$2, $5, $10].
Patients will receive one of the following amounts for a post-survey incentive [$20, $25, $28, $30]. All patients who complete the survey will receive at least $20 in compensation.

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):

Participants who request an at-home test, as well as matched sample of participants who do not request a test will be asked to complete a survey 3 months after becoming eligible to request their first at-home test. This survey request will have a [$0,$2, $5, $10] pre-survey incentive included. Participants who complete the survey will receive [$20, $25, $28, $30].

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):

[$0,$2, $5, $10] pre-survey
[$20, $25, $28, $30] post completion of survey

d. If applicable, explain plan for prorating payments if participant does not complete the study:

na

7. HIPAA and the Covered Entity

1. **Does this study involve Protected Health Information (PHI) or de-identified health information?**
   ● **Yes** ○ No

   a. **Select the method(s) of authorization that will be used:**

   Waiver or Alteration of Authorization

   b. **Will PHI be disclosed outside the Covered Entity?**
   ● **Yes** ○ No

   To whom?
   The National Institutes of Health RADx UP Coordinating and Data Collection Cetner

   And for what purposes?
   The data collected by SCALE UP Utah II, as well as the data collected by all of RADx-UP sponsored projects, will be used by the National Institutes of Health to help speed innovation in the development and implementation of COVID-19 testing. One of the priorities for RADx is building the RADx Data Hub, a national resource of RADx-generated research data that can help researchers and public health officials better understand the impact of the pandemic, including the outcomes, the disparities, and the possible solutions. The data shared from SCALE UP Utah II will contribute towards this mission.

Does this study involve any of the following:

2. **The investigational use of a drug?**
   ○ Yes ● **No**
   Mark yes, for an expanded access application.

3. **The investigational use of a medical device or humanitarian use device?**
   ○ Yes ● **No**
   Mark yes, for an expanded access application.

4. **The investigational use of a dietary supplement, food, or cosmetic?**
   ○ Yes ○ No

5. **Is this an investigator-initiated drug or device trial lead by the Principal Investigator'**
   ○ Yes ● **No**
   All investigator-initiated drug or device trials are required to have a full research protocol attached to the Documents and Attachments page.

6. **Will this study involve the use of an imaging modality from the department of Radiology?**
   ○ Yes ○ No

7. **Exposure to radioisotopes or ionizing radiation?**
   ○ Yes ● **No**

8. **Genetic testing and/or analysis of genetic data?**
   ○ Yes ● **No**

9. **Creating or sending data and/or samples to a repository to be saved for future research uses?**
   ● **Yes** ○ No

10. **Are you:**
    - **Collecting samples of blood, organs or tissues from participants for research purposes;**
    - **Introducing Recombinant or Synthetic Nucleic Acids (e.g. viral vectors, oligonucleotides) or cells containing recombinant nucleic acids (e.g. CAR-T) into participants; OR**
    - **Introducing other biological materials (e.g. bacteria, viruses) into participants.**

    ○ Yes ● **No**

11. **Does this study involve any of the following?**
    - **Cancer Patients**
    - **Cancer Hypothesis**
    - **Cancer risk reduction**
    - **Cancer prevention**

    ○ Yes ● **No**

12. **Any component of the Clinical and Translational Science Institute (CTSI)?**
    ● **Yes** ○ No

    The Clinical Research Center (CRC)?
    ○ Yes ● **No**

IRB_00150669 **Created:** 1/10/2022 7:14 AM

PI: Guilherme Del Fiol MD, PhD **Submitted:** 3/21/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

Request for Waiver or Alteration of Authorization

Request for Waiver of Authorization for Recruitment Only

This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.

Other Requests for Waivers of Authorization:

- *Click "Add" below to add a new waiver request to this application.*
- *Click the waiver name link to edit a waiver that has already been created.*
- *To delete a waiver request, contact the IRB.*

	Date Created	Type of Request	Purpose of Waiver Request
View	2/25/2022	Waiver of Authorization	The purpose of this waiver of authorization is to cover the use of collected EHR data and USIIS data for the randomization of patients in a research intervention, and establish cohort selection for research intervention without their authorization.
View	5/3/2022	Waiver of Authorization	The purpose of this waiver of authorization is for the use of EHR data and USIIS data after the intervention to analyze which patients, of those randomized into interventions, received COVID-19 tests and/or vaccinations.

Request for Waiver or Alteration of Authorization

1. **Purpose of the Waiver Request:**
The purpose of this waiver of authorization is to cover the use of collected EHR data and USIIS data for the randomization of patients in a research intervention, and establish cohort selection for research intervention without their authorization.

2. **Type of Request:**
Waiver of Authorization

3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).**
We plan to keep links to patient's names, date of birth, contact information, address, demographic information, insurance status, tobacco use status, medical record number (MRN), encounter diagnoses, COVID-19 lab test orders, COVID-19 lab test results, outcome of vaccination, guarantor status, communication preferences, and translator services required.

4. **Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives:**
The requested PHI data, including the COVID-19 testing and vaccination outcomes, enable the objective of increasing COVID-19 screening, testing, and vaccinations in marginalized populations. Without this linked data, it would be impossible to measure the effectiveness and impact of the research.

5. **Explain why the research could not practicably be conducted without the waiver of authorization.** *For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."*
If the study team had to obtain authorization, the research could not be conducted because of the sheer volume of the study as well as the fast timeframe due to the COVID-19 pandemic. The partnering CHCs see over 165,000 patients each year. It would be impossible to contact every patient who had visited a CHC in the past three years to authorize use of their EHR data. It is estimated that approximately 118,000 patients could be part of this intervention. It would be impossible for the study team to contact all of these participants, who will be located across the state of Utah, and obtain authorization in the time necessary for meaningful use of COVID-19 test and vaccination results. If this authorization to use test result data were necessary, it would not be feasible to conduct this research.

6. **Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access:**
All data will be stored on University of Utah HIPAA Compliant storage. Only staff members who will need PHI in order to carry out study procedures will have access to participant identifiers and complete contact information.

7. **The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention:**
Identifiers will be retained until research analyses and data collection are completed in entirety. The PHI will be destroyed when the study is officially closed

and research goals are completed. Until that time, the identifiers/PHI will continue to be stored.

8. **Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:**
   All information will be stored in a locked cabinet or password protected computers on HIPAA compliant University of Utah storage. Only individuals who need PHI to conduct study procedures will have access to patient identifying information.

Request for Waiver or Alteration of Authorization

1. **Purpose of the Waiver Request:**
The purpose of this waiver of authorization is for the use of EHR data and USIIS data after the intervention to analyze which patients, of those randomized into interventions, received COVID-19 tests and/or vaccinations.

2. **Type of Request:**
Waiver of Authorization

3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).**
We plan to keep links to patient's names, date of birth, contact information, address, demographic information, insurance status, tobacco use status, medical record number (MRN), encounter diagnoses, COVID-19 lab test orders, COVID-19 lab test results, COVID-19 vaccine orders, guarantor status, communication preferences, and translator services required.

4. **Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives:**
The requested PHI data, including the COVID-19 testing and vaccination outcomes, enable the objective of increasing COVID-19 screening, testing, and vaccinations in marginalized populations. Without this linked data, it would be impossible to measure the effectiveness and impact of the research.

5. **Explain why the research could not practicably be conducted without the waiver of authorization.** *For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."*
If the study team had to obtain authorization, the research could not be conducted because of the sheer volume of the study as well as the fast timeframe due to the COVID-19 pandemic. The partnering CHCs see over 165,000 patients each year. It would be impossible to contact every patient who had visited a CHC in the past three years to authorize use of their EHR data. It is estimated that approximately 118,000 patients could be part of this intervention. It would be impossible for the study team to contact all of these participants, who will be located across the state of Utah, and obtain authorization in the time necessary for meaningful use of COVID-19 test and vaccination results. If this authorization to use test result data were necessary, it would not be feasible to conduct this research.

6. **Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access:**
All data will be stored on University of Utah HIPAA Compliant storage. Only staff members who will need PHI in order to carry out study procedures will have access to participant identifiers and complete contact information.

7. **The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention:**
Identifiers will be retained until research analyses and data collection are completed in entirety. The PHI will be destroyed when the study is officially closed

and research goals are completed. Until that time, the identifiers/PHI will continue to be stored.

8. **Describe the measures you will take to ensure the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:**
   All information will be stored in a locked cabinet or password protected computers on HIPAA compliant University of Utah storage. Only individuals who need PHI to conduct study procedures will have access to patient identifying information.

Information for Accounting of Disclosures

1. **Earliest planned date of disclosure:** 1/9/2023
2. **Latest planned date of disclosure:** 12/30/2023
3. **Name and address of the entity or person outside of the Covered Entity who will receive the Protected Health Information:**
   Duke Clinical Research Institute on behalf of the National Institute on Minority Health and Health Disparities of the National Institutes of Health.
   PI: Michael Cohen-Wolkowiez, MD
   Durham, North Carolina
4. **A brief description of the PHI disclosed:**
   Patient demographics such as name, DOB, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information. Patient information pertaining to COVID-19 such as symptoms, test results, and vaccinations. Additional patient information including health, education, family, home, relationships, and social life.
5. **A brief statement of the purpose of the disclosure that reasonably informs the individual whose information is disclosed of the basis for the disclosure:**
   This information will only be disclosed to Duke if the patient consents to have their information disclosed. Patients will receive a consent cover letter that details the scope of information to be disclosed as well as the purpose.
   The purpose of disclosure is to aggregate this patient information with all of the RADx UP participants to better understand the risks of COVID-19 on underserved population and how to best help meet these needs.

Data & Tissue Banking

1. **Select the items that will be banked:**
   - ☐ Biological samples
   - ☑ **Data**

   List all the specific, participant information (identifiable and non-identifiable) that will be contributed to the repository (e.g., name, date of birth, phone number, age, gender, diagnosis, treatment status, outcome, date of collection, etc.):
   Patient demographics such as name, DOB, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information. Patient information pertaining to COVID-19 such as symptoms, test results, and vaccinations. Additional patient information including health, education, family, home, relationships, and social life. The specific survey that will be administered by the survey collection company is attached in the documents section. Only data that is consented to be sent to the NIH via Duke University will be banked.

2. **What type(s) of future research will be allowed on the data/samples?** These data will be available for "General Research Use."

3. **Who manages the repository and where will the data/samples be stored?**
   The data will be submitted by the University of Utah to the RADx-UP Coordination and Data Collection Center who will process the data and then submit it to the RADx-UP Data Hub which is managed by the National Institutes of Health.

4. **Indicate whether the data/samples in the repository will be identifiable directly or through a code/link.**

   a. **Select one of the following options:**
   OPTION 2: Some data/samples will be identifiable and some data/samples will be de-identified to one or more individuals who have responsibilities to manage or oversee the repository.

   b. **If you selected OPTION 1 or 2 above, describe the process for managing the identifiable data:**

   ### Who will manage and have access to the identifiable data?
   RADx staff who are approved by a research ethics committee to work with these data

   ### Where will the data be kept?
   The data will be kept by the RADx Data Hub which is managed by the National Institutes of Health. Data will be stored on protected, secure computer systems with limited access. All access will employ a password and multi-factor authentication.

   ### How will the data be kept confidential?
   All data will be kept on a secure database with limited access. All access will employ a password and multi-factor authentication.

   c. **If you selected OPTION 2 or 3 above, describe the process for de-identifying the data/samples:**

   ### Who will de-identify the data/samples?
   Participants will be able to select on the consent form whether they submit identifiable information or not. If participants choose to not submit identifiable information, no identifiable information will be shared.

   ### When will the data/sample be de-identified?
   Participants will be able to select on the consent form whether they submit identifiable information or not. If participants choose to not submit identifiable information, no identifiable information will be shared.

5. **Describe the procedures for participants to withdraw their data/samples from the repository. If participants will not be able to withdraw their samples, please provide an explanation:**
   There is no current procedure for participants to withdraw data from the NIH repository. If a patient were to contact the study to withdraw their data, the University study staff would work with the NIH to withdraw the participant's data.

6. **Will future research results or findings be communicated to the participants?**
   ○ Yes ● **No**

7. **Describe the procedures for other researchers to obtain data/samples from the repository for use in future research.**
   Any future researchers wanting to do secondary data analysis with the data in the repository would need to apply for data access using the NIH dbGaP controlled-data access system.

8. Resources and Responsibilities

1. * **State and justify the qualifications of the study staff:**

SCALE-UP Utah brings together partners with experience and expertise in the design, adaptation, implementation, and evaluation of health care system interventions, including among Utah CHCs, as well as an extensive record of collaboration on multiple projects. Many of the partners working on SCALE-UP Utah II are also working on multiple COVID-19 projects and therefore have acquired additional experience that is transferable to the content of this project.

This project is being led by two MPIs. Overall the MPIs are responsible for leading the planning, designing, and implementation of the project protocol, accumulation and interpretation of data, presentation of results, and ensuring that systems are in place to guarantee institutional compliance with US laws, and DHHS and NIH policies. Together the MPIs have significant experience in leading complex multi-level interventions, specifically involving EHR data, Community Health Clinics, behavioral treatment interventions, and large granting agencies.

In addition to the MPIs, this project engages seven Co-Is. The Co-Is will use their targeted expertise to support the MPIs in guiding the project through the funding cycle. Together the Co-Is have significant experience in bioinformatics, community interventions, sociotechnical assessments and workflows, and behavioral intervention adaptations. All of the Co-Is have the necessary training and experience to help facilitate the implementation and oversight of a large multi-level community intervention.

Additional study staff includes a statistician team, a software engineering team, a community health education specialist, an intervention trainer, a data manager, a project manager, and an epidemiologist.

The statistician team will conduct power calculations, provide statistical oversight in developing study design, conduct statistical simulations, and incorporate new statistical methods from the literature as needed throughout the funding period of the project. The statisticians on the team are PhD level researchers with extensive experience in population health science and biostatistics.

The software engineering team has over 50 years of combined experience in health-related software architecture and management. This team will be responsible for building, adapting, and implementing all the necessary software infrastructure to support the technical components of the project. The three engineers on this team have experience working with each other as well as with the MPIs and Co-Is on this study.

This study is utilizing one Community Health Education Specialist (CHES) to provide technical assistance and support for the Community Health Workers (CHW) acting as Patient Navigators for the patient navigation arm of this intervention. This includes providing training for the CHWs, identifying resources for patients who face barriers to testing, and ensuring that the interventions and protocols are appropriate for the patients included in this study. The CHES on this study, has extensive experience working with communities around education and interventions as well as in planning and implementing community health needs assessments (CHNAs). The CHES will be supervised by a licensed psychologist specialized in training interventionists.

The data manager for this project is responsible for creating a project database to house all data collected for the project, develop data dictionaries and coding manuals, perform data quality checks, clean all data, harmonize data, and ensure all common metrics are inappropriate format to be submitted to RADx-UP Coordinating and Data Collection Center as required, and assist in analyzing data for project reports and peer-reviewed manuscripts. The data manager is a highly qualified with experience in public health including COVID-19 intervention research.

The project manager for this project is responsible for facilitating project progress with all project partners and provide day to day management of all aspects of the project including: obtaining Institutional Review Board Approval and executing data use agreements between project partners, coordinating with AUCH to schedule clinic workflow assessments, usability assessments, and clinic practice team training, scheduling and coordinating Community and Study Advisory Committee Meetings, developing and refining data collection procedures, and coordinating all data collection and reporting. The project manager has experience in human centered design research, working on collaborative interdisciplinary teams, and providing project management for complex iterative research projects including several other COVID-19 projects.

The Epidemiologist for this project is responsible for advising the project team members on the most recent clinical and public heath recommendations from the CDC and the Utah Department of Health. The Epidemiologist has extensive experience in disease epidemiology and public health engagement.

In addition to the study teams, this project will benefit from the administrative assistance of the Center for HOPE at the Huntsman Cancer Institute. This includes assistance for investigators and staff in coordinating travel, agreements, meetings, reports, and financial materials between the University of Utah and other collaborators.

2. * **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   Research staff will regularly review protocols with participating CHCs to ensure appropriate protocol adherence. Research staff will meet regularly with MPIs to discuss issues, concerns, and study progress on a monthly or more frequent as needed basis. All U of U staff is CITI and HIPAA trained and certified for the protection of human subjects, proper data handling techniques, and good clinical practices.

3. * **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**

   The study will take place within 11 Community Health Center (CHC) systems across Utah. Within those CHCs there are 35 different clinics. The CHCs and clinics are listed here:

   Enterprise Valley Med Clinic: Enterprise Valley Medical Clinic

   Midtown Community Health Centers: Davis County Medical and Dental Clinics, Hope Homeless Health Center, Midtown Logan Clinic, James Madison Elementary Clinic, Midtown Children's Clinic (18 and under), Midtown Community Health Center – Adams, and Midtown South Salt Lake Community Health Center

   Family Health Care (FHC): Cedar City East Clinic, Hurricane Clinic, Integrated Cedar City Clinic, St George Downtown Clinic, St George Millcreek High School Clinic

   Green River Medical Center: Green River Medical Center

   Carbon Medical Service: Carbon Medical clinic and The Helper Clinic

   Wayne Community Health Center: Bicknell Clinic and Kazan Memorial Clinic

   Utah Partners for Health (UPFH): Mid-Valley Health Clinic, Utah Partners for Health Family Health Clinic - West Jordan, Utah Partners for Health Mobile Clinic

   FourPoints Health: Kanosh Community Health Center and Richfield Community Health Center

   Mountainlands Community Health: East Bay Health Center, Mountainlands Family Health Center, Mountainlands Family Health Center –Payson, Mountainlands Family Health Center – Vernal, Mountainlands Family Health Center - West Park

   Bear Lake Community Health Center: Bear Lake Community Health Center - Garden City, Box Elder Community

Health Center - Brigham City, Cache Valley Community Health Center - North Logan, Cache Valley Community Health Center - Providence

and Wasatch Homeless Health Care, Inc.: Fourth Street Clinic and Fourth Street Mobile Medical Clinic

Data will be collected via reports from the CHCs via the Association for Utah Community Health (AUCH).The University of Utah will administer text messaging/conversational agent interface and phone coaching. Patient randomization and data analysis will occur at the University of Utah.
The research team has verified that each participating clinic has a published Notice of Privacy Practice which states that patient's Protected Health Information (PHI) with patient identifiers can be disclosed for research without patient consent.

4. * **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**

   Not applicable.

5. * **How will adverse events, unanticipated problems, interim results, and changes to the research be communicated between the participating sites and the Principal Investigator?**

   Any adverse events, unanticipated problems, interim results, and changes to the research will be communicated between participating sites and the principal investigator at weekly meeting attended by PI, CO-Is, project staff, and partner representatives including AUCH and UDOH. Pressing matters will be handled through direct communication from the PI, Program Manager, and participating sites via email, phone calls, or virtual meetings.

IRB_00150669 **Created:** 1/10/2022 7:14 AM

PI: Guilherme Del Fiol MD, PhD **Submitted:** 3/21/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document(Highlighted Changes)

Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Parental Permission Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Assent Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

VA Consent Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Grant Application:

The Federal Government is a direct or indirect sponsor of your research. You are required to provide a copy of the grant proposal, grant award, or sub-award.

By submitting to the IRB, you are confirming the grant and the study protocol are consistent (Design, Study Population, Study Objectives and Goals, Test Interventions and Procedures, etc.)

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Literature Cited/References:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Other Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

IRB_00150669 **Created:** 1/10/2022 7:14 AM

PI: Guilherme Del Fiol MD, PhD **Submitted:** 3/21/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

Finish Instructions

Finish Instructions

1. **To view errors, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**

Electronic
RESEARCH INTEGRITY AND COMPLIANCE
THE UNIVERSITY OF UTAH

Date: Thursday, September 5, 2024 3:42:17 PM Print Close

IRB_00150669 - AM_Adding AUCH as study site; remove survey; remove NIH data transfer

Created: 10/18/2022 9:15 AM

AM_00046366
1. Amendment Type

PI: Guilherme Del Fiol

Submitted: 11/2/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

1. Amendment Introduction

Brief Description of the Study: (This will populate from original application)

SCALE-UP II is a state-wide, pragmatic study conducted among 11 Community Health Center (CHC) systems and 38 clinics across Utah. These CHCs serve low socioeconomic status, racially/ethnically diverse, and rural/frontier populations. The long-term objective of SCALE-UP II is to increase the reach, uptake, and sustainability of COVID-19 testing among underserved populations. Through RADx-UP Phase I funding (SCALE-UP Utah), the team has established population health management (PHM) interventions that have been used since Jan 2021 to increase the uptake of COVID-19 testing and vaccination among CHC patients. Interventions are based on a PHM approach that uses widely available technology (i.e. cell phones and text messaging). SCALE-UP II will both build on SCALE-UP Utah PHM interventions and investigate novel interventions (i.e., Conversational Agents; Proactive vs. Reactive Patient Navigation) that are tailored to address individuals' hesitancy factors and that work at the interplay between vaccination and testing.

SCALE-UP II builds on long standing partnerships among the University of Utah Clinical and Translational Science Institute (UofU CTSI), Association for Utah Community Health (AUCH), CHCs, and the Utah Department of Health (UDOH). CTSI and SCALE-UP II investigators are leading several COVID-19 initiatives that drive public health response and state government policies in Utah. Thus, the UofU team is uniquely positioned to lead this project.

SCALE-UP II will implement and evaluate practical, accessible, and scalable PHM interventions to increase COVID-19 testing and vaccine uptake based on the best evidence available, patients' specific barriers and hesitancy factors, and extensive collaboration with CHCs, AUCH, and UDOH:

1. **Text Messaging (TM):** bidirectional text messaging to connect patients to vaccination or mailed at-home rapid test kits for use as needed.
2. **Conversational Agent (CA):** automated, scripted and interactive agent used to mimic human interaction to: 1) elicit specific hesitancy factors and barriers to testing; 2) provide individually tailored information to address hesitancy and barriers; and 3) offer a connection to mailed at-home rapid test kits.
3. **Patient Navigation (PN):** phone call from a community health worker to help address hesitancy and access barriers, and to offer at-home rapid test kits. Two types of PN will be tested: **Reactive PN** (RPN) will contact only those patients who reply YES to a TM/CA message. **Proactive PN** (PPN) will contact all patients regardless of their responding or not to the TM/CA messaging.

Prior to randomization, patients will be triaged into one of two studies based on self-reported ownership of a smart phone with internet access.

The primary outcome, Testing, captures whether patients actually test with the mailed at-home test kit.

Secondary outcomes include: ***Time-To-Vaccine*** (time-to-event outcome) as well as several implementation outcomes including ***Reach-Engage Testing*** (proportion of patients that reply to an offer to receive an at-home rapid test kit) and ***Reach-Accept Testing*** (proportion of patients that accept an offer to receive an at-home test kit). A similar set of implementation outcomes will be measured for vaccination (i.e., ***Reach-Engage Vaccine*** *and* ***Reach-Accept Vaccine***).

1. **Name of Amendment:**
   Use a name that will make it easy to identify the contents of the amendment. You may use

information such as the sponsor amendment number or an internal tracking number.
Adding AUCH as study site; remove survey; remove NIH data transfer

2. **Type of Amendment (check all that apply):**

Administrative changes:

Changes to study procedures:

Changes to consent, parental permission, or assent documents

Changes to the risk/benefit profile and/or participant safety parameters

3. **Current Status of the Study:**
Open for Enrollment

4. **Total Number of Participants Enrolled To Date**
At Utah: 0
All Centers: 0

2. Amendment Description

You have indicated that the following types of changes are being made:

Administrative changes:

Changes to study procedures:

Changes to consent, parental permission, or assent documents

Changes to the risk/benefit profile and/or participant safety parameters

1. **What changes are being made? List and number each change, grouping similar changes together.**

   1. Administrative changes

   a. We would like to add Association for Utah Community Health as a study site.

   2. Changes to study design and procedures:

   a. We would like to remove the CDE survey administered by a survey company

   b. We would like to remove the procedure for sending data to the NIH

2. **Describe the reason for each of the changes described above. List and number the reasons according to the list above.**

   1. Administrative changes

   a. We need to add the Association for Utah Community Health (AUCH) as a study site because AUCH employs the community health workers who work as patient navigators for this study.

   2. Changes to study design and procedures

   a. We need to remove the procedure for administering the CDE survey because we have not signed a contract or reliance agreement with a survey company yet. Our plan is to re-add this procedure once we have a contracted survey company.

   Because we are removing the administration of the CDE survey for this amendment, we have also removed information on the consent process page as well as the risks and benefits page.

   On the consent process page, we removed all consent language/processes that are tied to the CDE (3 month follow up) survey. This includes the online consent and the phone consent. We have left the waiver of consent language in the study because the waiver of consent is what allows for the review of patient's data at participating CHCs to establish cohort selection.

   On the risks and benefits page, we have removed all of the details about the compensation that are linked to the CDE (3 month follow up) survey. The only compensation in this study is for the CDE (3 month follow up) survey, therefore this amendment aims to remove the compensation.

   b. We need to remove the procedure for sending data to the NIH because we are waiting on details from the NIH regarding the secure handling and storage of these data. Once we receive these details, we will re-add this

procedure and fill out the data banking section and add safe harbor for sharing data.

3. **How does each change described above affect participants? List and number the effects according to the above list.**

   1. Administrative changes will have no effect on participants.

   2. Changes to study design will not have any effect on participants because we have not enrolled any participants yet.

4. **Will the modification(s), in the opinion of the local PI, increase or decrease the risk to participants?**
   Neither

   If the risk changes, provide justification:

5. **How will enrolled participants (current and past) be notified of this change?**
   N/A - No currently enrolled participants

   If Other, please explain:

6. **Which approved documents are affected by these changes?**
   There are no items to display

   If other, please list:
   n/a

7. **Which sections of the Update Study Application are affected by these changes?**
   2. Study Locations and Sponsors
   4. Study Information- question 6
   Consent Process
   6. Risks and Benefits
   7. HIPPA and the Covered Entity
   Information for Accounting of Disclosures

8. **Select all study locations that are affected by these changes.**

   Prior Approved Study Controlled Locations

Site Name	Investigator Name	Covered Entity
☐ Association of Utah Community Health	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
☐ University of Utah	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
☐ Elite Research LLC (Irvine Texas)	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

   New Sites

3. Report Forms

1. **Is this amendment related to information that meets the IRB reporting policy for unanticipated problems and non-compliance?**

   ○ Yes ● **No**

   If yes, a Report Form must also be submitted and then linked to this amendment. Link the related report form to the amendment application by clicking 'Attach'. Then select the related Report Form from the list.

   You can also submit a new Report Form from this amendment application by clicking 'New'. Follow the instructions for creating a new Report Form below.

ID	Name	Date Submitted	Status

6. Documents and Attachments

Approved eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
ID00000004(0.01)	0.01	6/21/2023 7:31 AM	6/21/2023 7:31 AM	ID00000004

Print View: IRB Draft Protocol Summary

Updated eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved
ICF_SCALE UP II_Final_English(0.01)	0.01	6/13/2023 8:53 AM	6/13/2023 8:53 AM	6/21/2023 7:31 AM
ICF_SCALE UPII_Final_Spanish(0.01)	0.01	6/13/2023 8:54 AM	6/13/2023 8:54 AM	6/21/2023 7:31 AM

Updated Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Parental Permission Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Parental Permission Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Assent Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Assent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved VA Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated VA Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Surveys, etc.:

Name	Version	Date Created	Date Modified	Date Approved
Patient survey_English(0.01)	0.01	12/19/2022 3:31 PM	12/19/2022 3:31 PM	3/26/2023 9:45 PM
Patient survey_Spanish(0.01)	0.01	12/19/2022 3:31 PM	12/19/2022 3:31 PM	3/26/2023 9:45 PM

Updated Surveys, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Company Protocol:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Company Protocol:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Investigational Brochure:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Investigational Brochure:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Grant Application:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Grant Application:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Literature/Cited References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Literature/Cited References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Current PI Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Updated PI Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Current Faculty Sponsor Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Faculty Sponsor Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
Text message and mailer text for survey recruitment_English(0.01)	0.01	12/19/2022 3:35 PM	12/19/2022 3:35 PM	3/26/2023 9:45 PM
Text message and mailer text for survey recruitment_Spanish(0.01)	0.01	12/20/2022 8:24 AM	12/20/2022 8:24 AM	3/26/2023 9:45 PM

Updated Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
Certified Translation Form -hci2212-1.pdf(0.01)	0.01	3/26/2023 9:44 PM	3/26/2023 9:44 PM	

Updated Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

IRB_00150669 - AM_Adding AUCH as study site; remove survey; remove NIH data transfer

Created: 10/18/2022 9:15 AM

AM_00046366
7. Finish

PI: Guilherme Del Fiol

Submitted: 11/2/2022

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

7. Instructions and Finish

1. To view errors in this application, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.

Changes to the Update Study Application

2. Be sure to make all proposed changes to the Update Study portion of the application by selecting the "Update Study" button located on the left side of the amendment or continuing review workspace, which will be available once you select the "Finish" button at the top or bottom of this page.

3. To attach updated or new documents with this application, you may access the Documents and Attachments page in the Update Study application.

4. If you are proposing changes to any ancillary applications (i.e. RDRC-HUS or RGE), you must access these applications through the Update Study application on the Ancillary Applications page. All changes to ancillary applications must be approved by the corresponding committee prior to IRB approval of the amendment.

Submitting the Completed Amendment Application

5. Selecting the “Finish” button alone will NOT submit the application to the IRB. You MUST also select the "Submit" option on the workspace after you've selected the "Finish" button. Only the PI can submit the application to the IRB.

6. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.

Electronic
RESEARCH INTEGRITY AND COMPLIANCE
THE UNIVERSITY OF UTAH

Date: Thursday, September 5, 2024 3:42:46 PM Print Close

IRB_00150669 - AM_Adding post-intervention survey and NIH transfer and removing PPN

Created: 12/1/2022 1:23 PM

PI: Guilherme Del Fiol

Submitted: 1/18/2023

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

AM_00046757
1. Amendment Type

1. Amendment Introduction

Brief Description of the Study: (This will populate from original application)

SCALE-UP II is a state-wide, pragmatic study conducted among 11 Community Health Center (CHC) systems and 38 clinics across Utah. These CHCs serve low socioeconomic status, racially/ethnically diverse, and rural/frontier populations. The long-term objective of SCALE-UP II is to increase the reach, uptake, and sustainability of COVID-19 testing among underserved populations. Through RADx-UP Phase I funding (SCALE-UP Utah), the team has established population health management (PHM) interventions that have been used since Jan 2021 to increase the uptake of COVID-19 testing and vaccination among CHC patients. Interventions are based on a PHM approach that uses widely available technology (i.e. cell phones and text messaging). SCALE-UP II will both build on SCALE-UP Utah PHM interventions and investigate novel interventions (i.e., Conversational Agents and Patient Navigation) that are tailored to address individuals' hesitancy factors and that work at the interplay between vaccination and testing.

SCALE-UP II builds on long standing partnerships among the University of Utah Clinical and Translational Science Institute (UofU CTSI), Association for Utah Community Health (AUCH), CHCs, and the Utah Department of Health (UDOH). CTSI and SCALE-UP II investigators are leading several COVID-19 initiatives that drive public health response and state government policies in Utah. Thus, the UofU team is uniquely positioned to lead this project.

SCALE-UP II will implement and evaluate practical, accessible, and scalable PHM interventions to increase COVID-19 testing and vaccine uptake based on the best evidence available, patients' specific barriers and hesitancy factors, and extensive collaboration with CHCs, AUCH, and UDOH:

1. **Text Messaging (TM):** bidirectional text messaging to connect patients to vaccination or mailed at-home rapid test kits for use as needed.
2. **Conversational Agent (CA):** automated, scripted and interactive agent used to mimic human interaction to: 1) elicit specific hesitancy factors and barriers to testing; 2) provide individually tailored information to address hesitancy and barriers; and 3) offer a connection to mailed at-home rapid test kits.
3. **Patient Navigation (PN):** phone call from a community health worker to help address hesitancy and access barriers, and to offer at-home rapid test kits. Two types of PN will be tested: **Request PN** (RPN) will contact only those patients who reply YES to a TM/CA message. No PN will have no contact from a patient navigator.

Prior to randomization, patients will be triaged into one of two studies based on self-reported ownership of a smart phone with internet access.

The primary outcome, Testing, captures whether patients actually test with the mailed at-home test kit.

Secondary outcomes include: ***Time-To-Vaccine*** (time-to-event outcome) as well as several implementation outcomes including ***Reach-Engage Testing*** (proportion of patients that reply to an offer to receive an at-home rapid test kit) and ***Reach-Accept Testing*** (proportion of patients that accept an offer to receive an at-home test kit). A similar set of implementation outcomes will be measured for vaccination (i.e., ***Reach-Engage Vaccine*** *and* ***Reach-Accept Vaccine***).

1. **Name of Amendment:**
   Use a name that will make it easy to identify the contents of the amendment. You may use

information such as the sponsor amendment number or an internal tracking number.
Adding post-intervention survey and NIH transfer and removing PPN

2. **Type of Amendment (check all that apply):**

Changes to study procedures:

Changes to consent, parental permission, or assent documents

Changes to the risk/benefit profile and/or participant safety parameters

Protocol Summary Revisions

3. **Current Status of the Study:**
Open for Enrollment

4. **Total Number of Participants Enrolled To Date**
At Utah: 2200
All Centers: 2200

2. Amendment Description

You have indicated that the following types of changes are being made:

Changes to study procedures:

Changes to consent, parental permission, or assent documents

Changes to the risk/benefit profile and/or participant safety parameters

Protocol Summary Revisions

1. **What changes are being made? List and number each change, grouping similar changes together.**

   1. Changes to study procedures

   a. We would like to add a post-intervention survey administered by a University of Utah approved vendor survey company. This survey would include a pre- and post-survey incentive. We will upload this survey in English and Spanish.

   b. Per our contract with our sponsor agency, NIH, we need to add language that details the transfer of identifiable patient data to the NIH with patient consent. Patient data will not be transferred without consent.

   c. We would like to change our intervention slightly to remove one type of patient navigation that we previously planned to include; Proactive Patient Navigation.

   d. We are uploading the new consent document for the post-intervention study. This will be in English and Spanish.

   e. We are uploading a copy of the text message and printed mailer that patients will receive to solicit survey participation. This will be in English and Spanish.

2. **Describe the reason for each of the changes described above. List and number the reasons according to the list above.**

   1. Changes to study procedures

   a. The post-intervention survey is being added to assess study outcomes and to gather patient data requested by our funding agency, the NIH.

   b. The consented transfer of data is being initiated to comply with our contract with our funding agency, the NIH.

   c. We are removing Proactive Patient Navigation due to resource constraints and to more appropriately test a resource conservation approach of Patient Navigation.

   d. This new consent document will more easily and directly explain the purpose of the survey as well as the implications of completing it. It is in Spanish as well as English so that it can be easily understood by patients who speak both languages.

   e. This text message and mailer is being added to appropriately inform the participants of the option to complete this survey.

3. **How does each change described above affect participants? List and number the effects according to the above list.**

1. Changes to study procedures

a. The post-intervention survey will have the following effect on participants who choose to complete the survey. 1- They will receive compensation in the form of cash and/or gift card. 2- They will spend 8-10 minutes completing a survey. The questionnaire is of little risk.

The post-intervention survey will have the following effect on participants who choose NOT to take the survey. 1- They will receive the cash pre-survey incentive.

b. The transfer of funding to the NIH will only effect participants who consent to have their data transferred. Those who consent will have their data transferred and stored at Duke University which is acting as the secure data hub for the NIH.

c. The removal of Proactive Patient Navigation will have no effect on participants

d. The changes to the consent document will have no effect on participants because no participants have seen the survey yet.

e. The addition of the text message and mailer have no effect on participants because no participants have seen the documents yet.

4. **Will the modification(s), in the opinion of the local PI, increase or decrease the risk to participants?**
Neither

If the risk changes, provide justification:

5. **How will enrolled participants (current and past) be notified of this change?**
Participants will not be notified

If Other, please explain:

6. **Which approved documents are affected by these changes?**
Consent, Parental Permission, or Assent Documents

If other, please list:

7. **Which sections of the Update Study Application are affected by these changes?**
Contacts and Title (Question 6)
Study Information
Consent Process
Risks and Benefits
HIPPA and the Covered Entity
Information for Accounting of Disclosures
Data Banking
Documents and Attachments

8. **Select all study locations that are affected by these changes.**

Prior Approved Study Controlled Locations

Site Name	Investigator Name	Covered Entity
☐ Association of Utah Community Health	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

Site Name	Investigator Name	Covered Entity
☐ University of Utah	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
☐ Elite Research LLC (Irvine Texas)	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

New Sites

3. Report Forms

1. **Is this amendment related to information that meets the IRB reporting policy for unanticipated problems and non-compliance?**

   ○ Yes ● **No**

If yes, a Report Form must also be submitted and then linked to this amendment. Link the related report form to the amendment application by clicking 'Attach'. Then select the related Report Form from the list.

You can also submit a new Report Form from this amendment application by clicking 'New'. Follow the instructions for creating a new Report Form below.

ID	Name	Date Submitted	Status

6. Documents and Attachments

Approved eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
ID00000004(0.01)	0.01	6/21/2023 7:31 AM	6/21/2023 7:31 AM	ID00000004

Print View: IRB Draft Protocol Summary

Updated eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved
ICF_SCALE UP II_Final_English(0.01)	0.01	6/13/2023 8:53 AM	6/13/2023 8:53 AM	6/21/2023 7:31 AM
ICF_SCALE UPII_Final_Spanish(0.01)	0.01	6/13/2023 8:54 AM	6/13/2023 8:54 AM	6/21/2023 7:31 AM

Updated Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Parental Permission Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Parental Permission Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Assent Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Assent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved VA Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated VA Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Surveys, etc.:

Name	Version	Date Created	Date Modified	Date Approved
Patient survey_English(0.01)	0.01	12/19/2022 3:31 PM	12/19/2022 3:31 PM	3/26/2023 9:45 PM
Patient survey_Spanish(0.01)	0.01	12/19/2022 3:31 PM	12/19/2022 3:31 PM	3/26/2023 9:45 PM

Updated Surveys, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Company Protocol:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Company Protocol:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Investigational Brochure:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Investigational Brochure:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Grant Application:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Grant Application:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Literature/Cited References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Literature/Cited References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Current PI Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Updated PI Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Current Faculty Sponsor Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Faculty Sponsor Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
Text message and mailer text for survey recruitment_English(0.01)	0.01	12/19/2022 3:35 PM	12/19/2022 3:35 PM	3/26/2023 9:45 PM
Text message and mailer text for survey recruitment_Spanish(0.01)	0.01	12/20/2022 8:24 AM	12/20/2022 8:24 AM	3/26/2023 9:45 PM

Updated Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
Certified Translation Form -hci2212-1.pdf(0.01)	0.01	3/26/2023 9:44 PM	3/26/2023 9:44 PM	

Updated Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

7. Instructions and Finish

1. To view errors in this application, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.

Changes to the Update Study Application

2. Be sure to make all proposed changes to the Update Study portion of the application by selecting the "Update Study" button located on the left side of the amendment or continuing review workspace, which will be available once you select the "Finish" button at the top or bottom of this page.

3. To attach updated or new documents with this application, you may access the Documents and Attachments page in the Update Study application.

4. If you are proposing changes to any ancillary applications (i.e. RDRC-HUS or RGE), you must access these applications through the Update Study application on the Ancillary Applications page. All changes to ancillary applications must be approved by the corresponding committee prior to IRB approval of the amendment.

Submitting the Completed Amendment Application

5. Selecting the “Finish” button alone will NOT submit the application to the IRB. You MUST also select the "Submit" option on the workspace after you've selected the "Finish" button. Only the PI can submit the application to the IRB.

6. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.

Date: Thursday, September 5, 2024 3:42:59 PM Print Close

IRB_00150669 - AM_Adding Elite as study site, changing n, adding updated consent docs

Created: 3/30/2023 10:08 AM

PI: Guilherme Del Fiol

Submitted: 6/6/2023

Title: SCALE UP Utah II: Community-Academic Partnership to Address COVID-19 Testing and Vaccination Among Utah Community Health Centers

AM_00047765
1. Amendment Type

1. Amendment Introduction

Brief Description of the Study: (This will populate from original application)

SCALE-UP II is a state-wide, pragmatic study conducted among 11 Community Health Center (CHC) systems and 38 clinics across Utah. These CHCs serve low socioeconomic status, racially/ethnically diverse, and rural/frontier populations. The long-term objective of SCALE-UP II is to increase the reach, uptake, and sustainability of COVID-19 testing among underserved populations. Through RADx-UP Phase I funding (SCALE-UP Utah), the team has established population health management (PHM) interventions that have been used since Jan 2021 to increase the uptake of COVID-19 testing and vaccination among CHC patients. Interventions are based on a PHM approach that uses widely available technology (i.e. cell phones and text messaging). SCALE-UP II will both build on SCALE-UP Utah PHM interventions and investigate novel interventions (i.e., Conversational Agents and Patient Navigation) that are tailored to address individuals' hesitancy factors and that work at the interplay between vaccination and testing.

SCALE-UP II builds on long standing partnerships among the University of Utah Clinical and Translational Science Institute (UofU CTSI), Association for Utah Community Health (AUCH), CHCs, and the Utah Department of Health (UDOH). CTSI and SCALE-UP II investigators are leading several COVID-19 initiatives that drive public health response and state government policies in Utah. Thus, the UofU team is uniquely positioned to lead this project.

SCALE-UP II will implement and evaluate practical, accessible, and scalable PHM interventions to increase COVID-19 testing and vaccine uptake based on the best evidence available, patients' specific barriers and hesitancy factors, and extensive collaboration with CHCs, AUCH, and UDOH:

1. **Text Messaging (TM):** bidirectional text messaging to connect patients to vaccination or mailed at-home rapid test kits for use as needed.
2. **Conversational Agent (CA):** automated, scripted and interactive agent used to mimic human interaction to: 1) elicit specific hesitancy factors and barriers to testing; 2) provide individually tailored information to address hesitancy and barriers; and 3) offer a connection to mailed at-home rapid test kits.
3. **Patient Navigation (PN):** phone call from a community health worker to help address hesitancy and access barriers, and to offer at-home rapid test kits. Two types of PN will be tested: **Request PN** (RPN) will contact only those patients who reply YES to a TM/CA message. No PN will have no contact from a patient navigator.

Prior to randomization, patients will be triaged into one of two studies based on self-reported ownership of a smart phone with internet access.

The primary outcome, Testing, captures whether patients actually test with the mailed at-home test kit.

Secondary outcomes include: ***Time-To-Vaccine*** (time-to-event outcome) as well as several implementation outcomes including ***Reach-Engage Testing*** (proportion of patients that reply to an offer to receive an at-home rapid test kit) and ***Reach-Accept Testing*** (proportion of patients that accept an offer to receive an at-home test kit). A similar set of implementation outcomes will be measured for vaccination (i.e., ***Reach-Engage Vaccine*** *and* ***Reach-Accept Vaccine***).

1. **Name of Amendment:**
   Use a name that will make it easy to identify the contents of the amendment. You may use

information such as the sponsor amendment number or an internal tracking number.
Adding Elite as study site, changing n, adding updated consent docs

2. **Type of Amendment (check all that apply):**

Administrative changes:

Changes to study design elements:

Changes to consent, parental permission, or assent documents

3. **Current Status of the Study:**
Open for Enrollment

4. **Total Number of Participants Enrolled To Date**
At Utah: 26876
All Centers: 26876

2. Amendment Description

You have indicated that the following types of changes are being made:

Administrative changes:

Changes to study design elements:

Changes to consent, parental permission, or assent documents

1. **What changes are being made? List and number each change, grouping similar changes together.**

   1. Administrative changes. We are adding Elite Research as a study site

   2. Changes to study design. We are changing our enrollment goal

   3. Updated consent documents (Spanish and English) to note that the survey is being conducted by Elite Research which is a University of Utah approved contract vendor.

2. **Describe the reason for each of the changes described above. List and number the reasons according to the list above.**

   1. Administrative changes are needed to add Elite Research as a study site. Elite Research is the UofU approved vendor who will be administering the patient surveys.

   2. Changes to study design. We need to change our enrollment goal to 43,325. This changed because less health centers signed up for the project than originally anticipated.

   3. Changes to consent document. We needed to update our consent documents to tell patients that the survey was being conducted by a survey agency that was contracted with the University of Utah.

3. **How does each change described above affect participants? List and number the effects according to the above list.**

   1. Administrative changes will have no effect on participants

   2. Study design changes will have no effect on participants

   3. Change to consent document will have no effect on participants because the survey has not been started yet.

4. **Will the modification(s), in the opinion of the local PI, increase or decrease the risk to participants?**
   Neither

   If the risk changes, provide justification:

5. **How will enrolled participants (current and past) be notified of this change?**

Participants will not be notified

If Other, please explain:

6. **Which approved documents are affected by these changes?**

Consent, Parental Permission, or Assent Documents

If other, please list:

7. **Which sections of the Update Study Application are affected by these changes?**

Study Location and Sponsors
Participants
Study Information- Statistical plan
Documents and Attachments

8. **Select all study locations that are affected by these changes.**

Prior Approved Study Controlled Locations

Site Name	Investigator Name	Covered Entity
☐ Association of Utah Community Health	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
☐ University of Utah	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
☐ Elite Research LLC (Irvine Texas)	Guilherme Del Fiol	Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

New Sites

3. Report Forms

1. **Is this amendment related to information that meets the IRB reporting policy for unanticipated problems and non-compliance?**

   ○ Yes ● **No**

   If yes, a Report Form must also be submitted and then linked to this amendment. Link the related report form to the amendment application by clicking 'Attach'. Then select the related Report Form from the list.

   You can also submit a new Report Form from this amendment application by clicking 'New'. Follow the instructions for creating a new Report Form below.

ID	Name	Date Submitted	Status

6. Documents and Attachments

Approved eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
ID00000004(0.01)	0.01	6/21/2023 7:31 AM	6/21/2023 7:31 AM	ID00000004

Print View: IRB Draft Protocol Summary

Updated eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved
ICF_SCALE UP II_Final_English(0.01)	0.01	6/13/2023 8:53 AM	6/13/2023 8:53 AM	6/21/2023 7:31 AM
ICF_SCALE UPII_Final_Spanish(0.01)	0.01	6/13/2023 8:54 AM	6/13/2023 8:54 AM	6/21/2023 7:31 AM

Updated Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Parental Permission Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Parental Permission Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Assent Forms:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Assent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved VA Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated VA Consent Forms:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Surveys, etc.:

Name	Version	Date Created	Date Modified	Date Approved
Patient survey_English(0.01)	0.01	12/19/2022 3:31 PM	12/19/2022 3:31 PM	3/26/2023 9:45 PM
Patient survey_Spanish(0.01)	0.01	12/19/2022 3:31 PM	12/19/2022 3:31 PM	3/26/2023 9:45 PM

Updated Surveys, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Company Protocol:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Company Protocol:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Investigational Brochure:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Investigational Brochure:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Grant Application:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Updated Grant Application:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Approved Literature/Cited References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Literature/Cited References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Current PI Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Updated PI Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV(0.06)	0.06	1/12/2011 3:19 PM	2/3/2015 8:03 AM	
NIH Biosketch(0.04)	0.04	1/12/2011 3:20 PM	2/3/2015 8:05 AM	

Current Faculty Sponsor Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Faculty Sponsor Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Updated Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
Text message and mailer text for survey recruitment_English(0.01)	0.01	12/19/2022 3:35 PM	12/19/2022 3:35 PM	3/26/2023 9:45 PM
Text message and mailer text for survey recruitment_Spanish(0.01)	0.01	12/20/2022 8:24 AM	12/20/2022 8:24 AM	3/26/2023 9:45 PM

Updated Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Approved Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
Certified Translation Form -hci2212-1.pdf(0.01)	0.01	3/26/2023 9:44 PM	3/26/2023 9:44 PM	

Updated Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

7. Instructions and Finish

1. To view errors in this application, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.

Changes to the Update Study Application

2. Be sure to make all proposed changes to the Update Study portion of the application by selecting the "Update Study" button located on the left side of the amendment or continuing review workspace, which will be available once you select the "Finish" button at the top or bottom of this page.

3. To attach updated or new documents with this application, you may access the Documents and Attachments page in the Update Study application.

4. If you are proposing changes to any ancillary applications (i.e. RDRC-HUS or RGE), you must access these applications through the Update Study application on the Ancillary Applications page. All changes to ancillary applications must be approved by the corresponding committee prior to IRB approval of the amendment.

Submitting the Completed Amendment Application

5. Selecting the “Finish” button alone will NOT submit the application to the IRB. You MUST also select the "Submit" option on the workspace after you've selected the "Finish" button. Only the PI can submit the application to the IRB.

6. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.