Study Title: Louisiana Community-Engagement Alliance (LA-CEAL)

1. Study aim, background, and design

In August 2020, Louisiana (LA) ranked first in the US for COVID-19 cases by population with a case rate of 2,960 per 100,000 and fifth in deaths by population with a death rate of 97 per 100,000.[1] Furthermore, there were disturbing demographic trends in LA with Blacks representing the highest percentage of cases (40.2%) and second highest percentage of deaths (48.7%).[2] At that time, vaccines for prevention of COVID-19 were in development.[3] To reduce COVID-19-related morbidity and mortality, an approved vaccine needed to be disseminated with rapid uptake in the community. Mistrust of the health care system and experimentation create barriers to rapid and widespread acceptance of novel COVID-19 preventive and therapeutic interventions (including vaccines) among underrepresented groups.[4] The objective of this study is to **rapidly implement and evaluate the HALT-COVID program designed to address barriers and increase knowledge about COVID-19, vaccines, and availability of trials that informs decision-making about willingness to participate (WTP) in COVID-19 prevention (e.g., vaccines) and therapeutic initiatives and trials in underrepresented Louisianians.**

To accomplish this objective, we will conduct a **randomized controlled trial** to test the effectiveness of HALT COVID educational outreach by HALT COVID Ambassadors. HALT COVID Ambassadors will receive training to answer common vaccine questions & address misconceptions; conduct motivational interviewing (which has shown promise for reducing vaccine hesitancy); implement basic behavioral economics and related strategies to remove barriers to vaccination; and assist with scheduling vaccine appointments. Participants will be identified via multiple recruitment strategies including:

- **Random sample drawn from FQHC EHR data downloads:** EHR data downloads of adult patients seen in the last year will be used to draw random samples of persons to be contacted by telephone.
- **In-clinic recruitment:** via LA-CEAL staff who will directly approach clinic patients to inform on study activities, gain consent and assess eligibility.
- **Snowball sampling techniques:** potential (i.e., persons who have been screened, regardless of final eligibility determination) and enrolled participants will have the opportunity to refer persons they feel may be interested in participating.
- **Referrals from partners (including FQHC, FBO, and pharmacy partners)**: persons will be recruited via flyers that are posted at partner locations or distributed at community events, in addition to in-person recruitment and telephone-based recruitment by partner staff using member/patient lists or other referrals.
- **Ambassador identification and enrollment**: HALT-COVID Ambassadors will have opportunities to recruit persons using contacts made during fieldwork and community events.
- **Internet (digital displays & video) and radio advertisements** developed and disseminated by communications and public relations partner.

Eligibility will be based on the following criteria: vaccine hesitancy, age ≥18, Black, able to understand and speak English, and willing to engage with the HALT COVID Ambassador via in-person or virtual sessions exploring their own questions and concerns about vaccines. A total of 100 individuals will be enrolled into the trial and randomized to intervention (engagement by the Ambassador over a 1-month period) or usual care (no extra engagement). Baseline, 1-month, and 2-month follow-up surveys will assess for change in vaccine hesitancy.

2. Subject Population

Using the following criteria, we will enroll up to 100 participants from patient populations of partner FQHCs:

> Inclusion criteria: Vaccine hesitancy; age >=18 years; Black; ability to understand and speak English; willingness to engage with the HALT COVID Ambassador via in-person or virtual sessions exploring their own questions and concerns about vaccines

Exclusion criteria: Unable or unwilling to give informed consent

Multiple strategies will be used to recruit participants including telephone calls to a random sample of adult patients served in the past year (identified in the EHR); in-clinic recruitment by LA-CEAL staff of clinic patients from partner FQHCs; snowball sampling methods, offering potential and enrolled participants the opportunity to refer others; referrals from FQHC, FBO pharmacy, and other partners using flyers, direct communication at partner locations and community events, and telephone-based recruitment to identify and recruit potential participants; Ambassador identification and enrollment during fieldwork and community events; and internet (digital displays and video) and radio advertisements.

Eligibility criteria will be confirmed prior to enrollment into the study.

3. Procedure

After obtaining verbal consent, study staff will verify participant contact information, collect alternate contact information for a friend or family member who is likely to be able to reach the participant in the event the study staff cannot, conduct a baseline questionnaire, and reveal the results of the randomization procedure conducted by the LA-CEAL Study and Data Coordinating Center staff. Participants will be randomly assigned to intervention (HALT COVID Ambassador engagement) or usual care. Participants randomized to the intervention will be engaged over a one-month period in discussions by the HALT COVID Ambassador; identified concerns or barriers around vaccination will be addressed, drawing upon the training and resources provided through the LA-CEAL program. We anticipate a total of 3-4 engagements over the month, each lasting 30 minutes to 1 hour. Discussions will take place in-person at a location mutually agreed upon by the participant and Ambassador, or virtually via telephone or web-based video platform (e.g., Zoom). Usual Care participants will not receive any additional outreach during this one-month period. After one month, all participants will be re-contacted via telephone by LA-CEAL staff to complete a month 1 follow-up survey. Following a one-month maintenance period (no intervention delivery), all participants will be re-contacted via telephone by LA-CEAL staff to complete a month 2, follow-up sustainability survey. Study staff will contact participants by text or phone to confirm and remind of all study and Ambassador visits.

4. Risks

The risk of physical, psychological, social, or legal harm associated with participation in all components of this study is minimal:

- Though not sensitive in nature and widely used in social science research, participants may feel uncomfortable responding to some of the survey questions; participants will be informed that they do not have to answer any question they do not want to answer and that they can stop participating at any time without penalty.
- Participants may find it inconvenient to take time to participate in the study. All study activities will be arranged at a time that is convenient for participants. The option to complete study activities via telephone or Zoom will also ease the burden of participation for participants.
- There is a small risk of unauthorized disclosure of participants' responses, which will be prevented by following a strict protocol for data handling and rigorous training of study staff:
    - All electronic study records will be stored with password protection. All paper study records will be locked in a secure study office. Data will be accessible only by study staff with approval from the PI.
    - The data will be retained without identifiers in a secure location for possible use in a future project, which will be consistent with the original research purpose.
    - Data may be shared with the NIH or other researchers upon request. Any data shared with the NIH or other researchers will not contain identifying information.
    - Identifiers will be stored in REDCap for the purposes of study management and follow-up. Study data will be stored separate from identifiers and a master key linking study data to identifiers will

be stored electronically in a separate REDCap database. Upon completion of all data collection and verification activities, records linking identifying information to study data will be destroyed.

5. Benefits

Individuals randomized to the intervention could benefit from engagement with the HALT COVID Ambassador which provides COVID-19 information and messages that may change their attitudes toward vaccines and remove barriers, thereby leading to vaccination and reduction in risk of severe COVID-19 infection. The knowledge to be gained may benefit society in general by providing evidence about the effectiveness of an approach for reducing vaccine hesitancy and increasing vaccine uptake.

6. Remuneration

Participants who complete the baseline and follow-up surveys will receive remuneration in the form of a $25 gift card for each survey completed (up to $75).

In addition, potential and enrolled participants will receive a $10 gift card for reimbursement of time used to recruit others (per person ultimately enrolled, up to five persons per referring individual).

Participants who are randomly assigned to the intervention will also receive remuneration in the form of a $15 gift card for each Ambassador session completed (up to $60).

7. Costs

There will be no costs to the participant for participating in this research study.

8. Consent process and documentation

Participants will be identified via multiple recruitment strategies:

- **Random sample drawn from FQHC EHR data downloads:** FQHC staff will query EHR records to generate a list of potentially eligible patients based on age and status (seen in last year). Only name and contact information will be listed on data downloads provided to LA-CEAL staff. We are requesting a *waiver of HIPAA Authorization* and a *waiver of informed consent* for this step in the recruitment process. A random sample of FQHC patients will be drawn from lists and contacted via telephone by LA-CEAL study staff. A recruitment script will be used to introduce the study and a consent script that explains the study purpose, procedures, risks and protections, and benefits will be read to interested patients. Verbal consent will be obtained and eligibility will be assessed before administration of the baseline survey. We are requesting a *waiver of documentation of informed consent* for this study activity given the nature of the risk associated with participating in the study (minimal) and the fact that most or all study activities will be conducted via telephone or web-based video platform (e.g., Zoom).
- **In-clinic recruitment:** LA-CEAL staff will approach clinic patients in private clinic rooms to inform on study activities, gain consent and assess eligibility. A recruitment script will be used to introduce the study and a consent script that explains the study purpose, procedures, risks and protections, and benefits will be read to interested patients. Verbal consent will be obtained and eligibility will be assessed before administration of the baseline survey. We are requesting a *waiver of HIPAA Authorization* and *waiver of documentation of informed consent* for this study activity given the nature of the risk associated with participating in the study (minimal).
- **Snowball sampling techniques:** potential (i.e., persons who have been screened, regardless of final eligibility determination) and enrolled participants will have the opportunity to refer persons they feel may be interested in participating. Study flyers and contact information for study staff will be provided to potential and enrolled participants for passing on to other potential participants. Those individuals will contact LA-CEAL study staff through the study telephone number. A recruitment script will be used to introduce the study and a consent script that explains the study purpose, procedures, risks and protections, and benefits will be read to interested patients. Verbal consent will be obtained and eligibility will be assessed before administration of the baseline survey. We are requesting a *waiver of HIPAA Authorization* and a *waiver of documentation of informed consent* for this study activity given the

nature of the risk associated with participating in the study (minimal) and the fact that most or all study activities will be conducted via telephone or web-based video platform (e.g., Zoom).

- **Referrals from partners (including FQHC, FBO, and pharmacy partners)**: persons will be recruited via flyers that are posted at partner locations or distributed at community events, in addition to in-person recruitment and telephone-based recruitment by partner staff using member/patient lists or other referrals. The IRB-approved recruitment script will be provided to partner staff for use in recruitment efforts. In addition, study flyers and contact information for study staff will be provided to partners for passing on to potential participants. Interested individuals will contact LA-CEAL study staff through the study telephone number. A recruitment script will be used to introduce the study and a consent script that explains the study purpose, procedures, risks and protections, and benefits will be read to interested patients. Verbal consent will be obtained and eligibility will be assessed before administration of the baseline survey. We are requesting a *waiver of HIPAA Authorization* and a *waiver of documentation of informed consent* for this study activity given the nature of the risk associated with participating in the study (minimal) and the fact that most or all study activities will be conducted via telephone or web-based video platform (e.g., Zoom).
- **Ambassador identification and enrollment**: HALT-COVID Ambassadors will have opportunities to refer persons using contacts made during fieldwork and community events. The IRB-approved recruitment script will be provided to Ambassadors for use in recruitment efforts. In addition, study flyers and contact information for study staff will be provided to Ambassadors for passing on to potential participants. Interested individuals will contact LA-CEAL study staff through the study telephone number or will give their contact information (name and phone number) to the Ambassador for contact by LA-CEAL study staff. A recruitment script will be used to introduce the study and a consent script that explains the study purpose, procedures, risks and protections, and benefits will be read to interested patients. Verbal consent will be obtained and eligibility will be assessed before administration of the baseline survey. We are requesting a *waiver of HIPAA Authorization* and a *waiver of documentation of informed consent* for this study activity given the nature of the risk associated with participating in the study (minimal) and the fact that most or all study activities will be conducted via telephone or web-based video platform (e.g., Zoom).
- **Internet (digital displays & video) and radio advertisements:** A communications and public relations firm will develop and disseminate internet (using both video and digital displays) and radio advertisements. Prospective participants will be directed to self-complete a virtual pre-screening/interest form. Those meeting initial inclusion criteria and providing contact information will be contacted by the LA-CEAL research team. A recruitment script will be used to introduce the study and a consent script that explains the study purpose, procedures, risks and protections, and benefits will be read to interested patients. Verbal consent will be obtained and eligibility will be assessed before administration of the baseline survey. We are requesting a *waiver of documentation of informed consent* for this study activity given the nature of the risk associated with participating in the study (minimal) and the fact that most or all study activities will be conducted via telephone or web-based video platform (e.g., Zoom).

9. References

1. Centers for Disease Control and Prevention. CDC COVID Data Tracker. https://www.cdc.gov/covid-data-tracker/#cases. Published 2020. Updated Aug 19 2020. Accessed Aug 19 2020.
2. Louisiana Department of Health. COVID-19. https://ldh.la.gov/Coronavirus/. Published 2020. Updated Aug 19 2020. Accessed Aug 19 2020.
3. World Health Organization. DRAFT landscape of COVID-19 candidate vaccines. World Web site. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines. Published 2020. Accessed Aug 24 2020.
4. Schaffer DeRoo S, Pudalov NJ, Fu LY. Planning for a COVID-19 Vaccination Program. *Jama.* 2020.

Statistical Analysis Plan

Baseline demographics will be summarized using means and standard deviations or proportions as appropriate. Between-group differences in the proportions of participants for each outcome will be tested using Pearson's chi-squared tests.