Getting to Yes: Increasing COVID-19 vaccination in Michigan

Community-Centered Interventions for Improved Vaccine Uptake for COVID-19 (CIVIC)

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National Clinical Trial (NCT) Identified #: NCT05096260

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Approved by IRB HUM00204174

Protocol Version #: v.12.0 – February 26, 2024

STATEMENT OF COMPLIANCE

This study will be carried out in accordance with Good Clinical Practice (GCP) as required by the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, and 21 CFR Part 56)
- NIH Clinical Terms of Award

All key personnel (all individuals responsible for the design and conduct of this study) have completed Human Subjects Protection Training. The protocol and informed consent form(s) will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form will be obtained before any participant is enrolled. Any amendment to the protocol will first go through IRB review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form, if this becomes applicable. (i.e. if there is a requested change to the consent form during the course of this study)

1 PROTOCOL SUMMARY

1.1 Synopsis

Title:	Getting to Yes! Michigan: Increasing COVID-19 vaccinations
Study Description:	This proposal, entitled Community-Centered Interventions for Improved Vaccine Uptake for COVID (CIVIC), is designed to directly address and decrease COVID-19 vaccine hesitancy and increase vaccine uptake among populations that experience COVID-19 related disparities. We will focus on the entirety of the state of Michigan, with a keen focus in four counties within Michigan where a disproportionate burden of COVID-19 within AA and LX communities, i.e., Wayne, Genesee, Kent and Washtenaw Counties. Using a community-based participatory research (CBPR) approach, CIVIC will leverage: its long term, community-based relationships through an established CBPR Steering Committee developed as a Community Engagement Alliance (CEAL) grant recipient, the University of Michigan CTSA (MICHR), and the expertise of our academic partners to identify and understand factors that contribute to COVID-19 vaccine hesitancy in AA and LX communities in Michigan.
Objectives:	1: Increase understanding of the barriers and drivers of vaccine uptake and hesitancy; 2: Increase vaccine uptake and decrease vaccine hesitancy through the implementation and evaluation of a multilevel, tailored intervention; and maintain, enhance, and evaluate the effectiveness of the CIVIC partnerships to equitably engage all partners.
Endpoints:	Primary Endpoint: Vaccination rate between baseline and 6-months Secondary Endpoints: Vaccination rate between baseline and 12 months

Study Population:	Adults (>18-years-old) living in the state of Michigan. We have recruited 30 churches into the intervention, and they will assist in the recruitment of subjects from each church alongside study team recruitment in the community. To achieve the goal of the study, we must recruit n = 800-1000 (400-500) intervention, (400-500) control) subjects. We expect an approximately equal distribution of gender. Demographics are expected to reflect local community populations from which we recruit.
Phase:	N/A
Description of Sites/Facilities Enrolling Participants:	Will recruit subjects from the community at events such as farmers markets, health fairs, social media, etc as well as from the thirty churches from the four target counties. We will also recruit with Data Direct, a U-M resource.
Description of Study Intervention:	Intervention designed as a randomized control trial implemented over 48 weeks. Intervention includes SMS/MMS messages tailored from a Baseline survey for people who are either unvaccinated/unboosted. Volunteers who are vaccinated may participate as vaccine champions to encourage participants to be vaccinated. If the fully vaccinated person has signed up prior to December 2022, they can complete 2 trainings to become a vaccine champion plus. They will reach out to participants that would like additional information from a vaccine champion plus. A fully vaccinated person enrolled after January 2023 will become a vaccine champion and will have the opportunity to complete the motivational interviewing training but won't interact with participants.
Study Duration:	48 weeks for intervention and manuscript preparation time
Participant Duration:	24 weeks
Related separate QI initiatives for this study	N/A

1.2 Schema

Crossover Individualized Randomized Control Trial

Randomization. At the time of randomization, eligible participants will be assigned a unique randomization number; no participant may begin intervention prior to randomization. Eligible participants will be randomized to Intervention or Control in a 1:1 manner, stratified by vaccination status (vaccinated [≥1 vaccine received] or unboosted or unvaccinated [0 vaccines received]). The study statistician will prepare the randomization schedule, using computer-generated permuted

block randomization with the block size(s) known only by the study statistician. A secure web-based application will be built that will be used by the coordinators to enter participant information (e.g., participant ID, stratification factor) and to obtain the randomization number.

Mock Randomization:

Randomization List 1: Vaccinated (≥1 vaccine received)

STRAT_NO	STRAT_LABEL	TRT_GROUP	TRT_ALLOCATION	RANDO_NO
1	Vaccinated (≥1 vaccine received)	A	Control	1327
1	Vaccinated (≥1 vaccine received)	A	Control	1330
1	Vaccinated (≥1 vaccine received)	B	Intervention	1333
1	Vaccinated (≥1 vaccine received)	B	Intervention	1336
1	Vaccinated (≥1 vaccine received)	A	Control	1339
1	Vaccinated (≥1 vaccine received)	B	Intervention	1342
1	Vaccinated (≥1 vaccine received)	B	Intervention	1345
1	Vaccinated (≥1 vaccine received)	A	Control	1348

Randomization List 1: Unboosted or Unvaccinated (0 vaccines received)

STRAT_NO	STRAT_LABEL	TRT_GROUP	TRT_ALLOCATION	RANDO_NO
0	Unboosted or Unvaccinated (0 vaccines received)	B	Intervention	1351
0	Unboosted or Unvaccinated (0 vaccines received)	A	Control	1354
0	Unboosted or Unvaccinated (0 vaccines received)	B	Intervention	1357
0	Unboosted or Unvaccinated (0 vaccines received)	A	Control	1360
0	Unboosted or Unvaccinated (0 vaccines received)	B	Intervention	1363
0	Unboosted or Unvaccinated (0 vaccines received)	A	Control	1366
0	Unboosted or Unvaccinated (0 vaccines received)	A	Control	1369
0	Unboosted or Unvaccinated (0 vaccines received)	B	Intervention	1372

Primary Outcome: Primary outcomes will be **vaccine completion** ((2mRNA or 1 J & J) + bivalent)
Secondary Outcome: Primary outcome is **additional vaccine dose** (0 to 1, 1 to 2, or 2 to 3)

We aim to enroll around 500 per arm (moderate effective size e.g., 20% vs. 32% rates in control vs. intervention arms).

1.3 Schedule of Activities (SoA)

Note: Times indicated in this table guide our study measures and time points. Our pilot work has shown that patient scheduling for activities requires flexibility to accommodate not only the study but the needs and schedules of patients. As such, times for data collection may show 'windows +/- x days). Exact time points of data collection will be documented in study logs, and also accounted for during analyses.

	Pre	Post

Event-Time Point	Baseline	Follow-up
Church Enrollment	X	
Individual Enrollment	X	
Baseline for unvaccinated	X	
Virtual training for recruited champions	X	
In-person training for recruited champions	X	
Post-intervention Survey		X

2 INTRODUCTION

2.1 Study Rationale

Like many states across the country, COVID-19 cases and deaths have impacted communities of color in Michigan at disproportionately higher rates than whites. A staggering reality is that while African Americans (AA) represent only 13.6% of Michigan's population, they represent 40% of the deaths from COVID-19.

- Half of the cases and deaths in Michigan occurred in Wayne County.
- Other Counties in the lower half of Michigan have similar disparities including Genesee, Washtenaw, and Kent.
- - In Genesee County, where AAs represent 20.3% of the population, they represent 35% of COVID-19 cases and 45% of deaths.
- - In Washtenaw County, nearly half of the cases to date are located in two majority low-income zip codes in the city of Ypsilanti. AA residents, who make up 12% of the Washtenaw population, disproportionately constitute more than a quarter of the cases.
- - And in Kent County, while 10.8% of the population is Latinx (LX), this ethnic group makes up 32.4% of COVID-19 cases.

Preliminary data from the state reveal that these disparities will likely worsen due to significant hesitancy, fear, mistrust and misinformation regarding the COVID-19 vaccine if nothing is done to change current trends. This proposal, entitled Community-Centered Interventions for Improved Vaccine Uptake for COVID-19 (CIVIC), is designed to directly address and decrease COVID-19 vaccine hesitancy and increase vaccine uptake among populations that experience COVID-19 related disparities. CIVIC/G2YMI will be offered to anyone in the state of Michigan, we will focus on the four counties within Michigan where a disproportionate burden of COVID-19 is within AA and LX communities, i.e., Wayne, Genesee, Kent and Washtenaw Counties. Using a community-based participatory research (CBPR) approach, CIVIC will leverage: its long term relationships with the communities involved, an established CBPR Steering Committee developed and the knowledge gained as a Community Engagement Alliance (CEAL) grant recipient, the resources and networks of the University of Michigan CTSA (MICHR), and the

expertise of our academic partners to identify and understand factors that contribute to COVID-19 vaccine hesitancy in AA and LX communities in Michigan.

This aim will develop and test interventions based on community-centered approaches to achieve a primary goal of increased vaccine uptake.

We will achieve this goal with the following aims:
1: Increase understanding of the barriers and drivers of vaccine uptake and hesitancy;
2: Increase vaccine uptake and decrease vaccine hesitancy through the implementation and evaluation of a multilevel intervention; and maintain, enhance, and evaluate the effectiveness of the CIVIC partnership to equitably engage all partners.

2.2 Background

Like many states across the country, COVID-19 cases and deaths have impacted communities of color in Michigan at disproportionate rates. A staggering reality is that while African Americans represent only 13.6% of Michigan's population, they represent 40% of the deaths from COVID-19. Half of the cases and deaths in Michigan occurred in Wayne County. Other Counties in the lower half of Michigan have similar disparities including Genesee, Washtenaw, and Kent. In Genesee County, where African Americans represent 20.3% of the population, 35% of COVID-19 cases and 45% of deaths are in these communities. In Washtenaw County, nearly half of the cases to date are located in two majority low-income zip codes in the city of Ypsilanti. African American residents, who make up 12% of the Washtenaw population, disproportionately constitute more than a quarter of the cases. And in Kent County, while 10.8% of the population is Hispanic or Latino, this ethnic group makes up 32.4% of COVID-19 cases. It is unquestionable that this crisis has exacerbated existing racial/ethnic inequity and health disparities in Michigan. Preliminary data from the state reveal that these disparities will likely worsen due to significant hesitancy, fear, mistrust, and misinformation regarding the COVID-19 vaccine if nothing is done to change current trends. This proposal, entitled Community-Centered Interventions for Improved Vaccine Uptake for COVID (CIVIC) is designed to directly address and decrease COVID-19 vaccine hesitancy and increase vaccine uptake among populations that experience health disparities. We will focus on the four counties within Michigan that were hardest hit and/or where a disproportionate burden is within AA and LX communities i.e., Wayne, Genesee, Kent and Washtenaw Counties. Using a community based participatory research (CBPR) approach, CIVIC will leverage its long term relationships with the community, an established Steering Committee, the resources and networks of the University of Michigan CTSA (MICHR), our status and knowledge gained as a Community Engagement Alliance (CEAL) grant recipient, and the expertise of our academic partners to identify and understand factors that contribute to COVID-19 vaccine hesitancy in African-American (AA) and Latinx (LX) communities in Michigan and develop and test interventions based on community-centered approaches to achieve a primary goal of increased vaccine uptake.

2.3 Risk/Benefit Assessment

Risk Likelihood: There is the rare potential risk that participants may be embarrassed or upset by questions in the questionnaires or interviews. Risks or discomforts from this research are minimal and may include discomfort with speaking to unvaccinated individuals about their barriers and beliefs about the COVID-19 vaccine.

Risk Seriousness: You have the option to not answer any questions that you feel is too sensitive. Questions were previewed by community members, religious and spiritual leaders, and those questions deemed too sensitive were removed.

Measures to minimize risk: Privacy is very important, and the study investigators use many safety measures to protect subject privacy.

Participation in this research is voluntary, and you may choose to withdraw at any time by contacting the study team at *gettingtoyesMI@med.umich.edu*

Participation in this research is confidential. All research data will be de-identified, and you will be identified by number and not by name. No information by which you can be identified will be released or published in connection with this study.

No information by which you can be identified will be released or published in connection with this study. In spite of all of the safety measures that we will use, however, we cannot guarantee that your identity will never become known.

Study paper data (i.e. consent forms and history forms will be stored in locked cabinets) and electronic data is stored on servers accessible via password-protected computers.

Study data will be stored in a relational database on a separate highly restricted secure server. Databases will be backed up daily to an offsite NAS storage device using automatic backup software that is available 24/7 except for scheduled maintenance. Only the primary investigators and other authorized research team members named in the approved IRB application will have access to the de-identified data. These standards will help ensure that violations of confidentiality will be minimal.

There is the potential risk that participants may be embarrassed or upset by questions in the questionnaires or interviews. Subjects will have the option to not answer any questions that they determine to be too sensitive.

The direct benefits of your participation may include:
- increased knowledge about the COVID-19 vaccine.

There are no immediate health benefits to the study subjects. This study, however, will provide important information about the beliefs, behaviors, sources of truth, and misinformation that drive COVID-19 vaccine uptake so that in the future others might benefit from this study.
Participants who wish to receive communication training will receive a link to the Articulate 360 training. Newly Enrolled (Post December 2022) Vaccine Champions will complete the virtual, MI-based, (Articulate) communications training only. No incentive will be paid to newly enrolled Vaccine Champions. Note: Currently enrolled (prior to December 2022) Vaccine Champions Plus will be trained on program specifics to aide in discussions with participants to answer questions regarding vaccination. They will receive abbreviated PEERRS training as well as Motivational Interviewing techniques. We will distribute vaccine champions plus initial $50 payment after a self-paced virtual and $50 for a live-virtual MI-based communication trainings.

Vaccine Champions Plus (those recruited prior to Dec 22) will be matched manually to unvaccinated/unboosted participants manually by the study team.

Link to Articulate Training: *https://rise.articulate.com/share/U3TRBPxQQKA5Vd8yOs4w6aVOtuq-FKyJ*

3 OBJECTIVES AND ENDPOINTS

1: Increase understanding of the barriers and drivers of vaccine uptake and hesitancy;

2: Increase vaccine uptake and decrease vaccine hesitancy through the implementation and evaluation of a multilevel intervention; and

3: Maintain, enhance, and evaluate the effectiveness of the CIVIC partnership to equitably engage all partners.

4 STUDY DESIGN

4.1 Overall Design

Overview and Study Design.

We will develop and test, with the active engagement of the CIVIC SC, the impact of a tailored mobile-optimized web intervention on vaccine uptake. Individually tailored interventions have consistently been shown to be more efficacious than group-level or static messages.

Building on several prior individually-tailored interventions we have developed for AAs, we designed a user-friendly, culturally-sensitive, interactive intervention that addresses key determinants of vaccine behavior—e.g., knowledge gaps, barriers, beliefs, values, ethnic identity, medical mistrust, discrimination, and communal responsibility. The comparison group will receive a mobile-optimized web program absent individual tailoring (i.e., standard, static content). Participants, (unboosted or unvaccinated) will be randomly assigned to each condition, for both Aims 2 and 3. The primary outcome will be self-reported COVID-19 vaccine uptake (at least one dose) after six months from the start of the Aim 2 study. To detect a 15% absolute difference in vaccine rates (.40 versus .55), we will require approximately 700 individuals at posttest (350 from intervention, 350 from control)

All intervention materials are available in English and Spanish including: the web-based program messages through testimonials, infographics, and links to other content, promotional materials.

App Structure.

The “App,” which will be web-based rather than a native program running in iOS or Android, will be optimized for use with various screen sizes, devices, and operating systems. This allows us to avoid the time and cost of developing and posting native versions in iOS/Swift and Android. To allow use across multiple device types (e.g., phone, PC, or tablet) without requiring participants to download an actual “App.” The mobile website is a hybrid, meaning that it is neither a truly native mobile application (because much of the computation is done via the web) nor purely web-based. Our team has built numerous similar sites and has extensive experience with Qualtrics, Cordova, CSS, HTML, Python, and Java, including projects by Drs. Resnicow and An. Users will “download” and bookmark the “App” which will “launch” upon clicking, mimicking a true App experience.

App Development.

The Center for Health Communications Research (CHCR), which will design the tailored web program for this study, has been at the forefront of theory-driven, culturally-tailored interventions for over 20 years. CHCR iteratively evaluates and improves the user experience throughout the development process, relying on a range of feedback methods including contextual interviews, focus groups, heuristic evaluation, and formal usability testing conducted in accordance with best practices outlined at usability.gov. As part of the project lifecycle, CHCR performs qualitative and quantitative evaluation of user experience with mature programs (e.g. system usability and paradata assessment) and the impact of user experience on intervention impact. A robust and refined project lifecycle, based on quality principles and modern agile development methodologies, guides all planning, development, and implementation activities. This standard process helps ensure well-conceived, high-quality products by defining goals, methods, and quality assurance procedures for each of the project’s stages. CHCR uses a standards-based, cross-platform, open-source application that enables the efficient creation, testing, and delivery of richly tailored communications. These communications may include individually-tailored

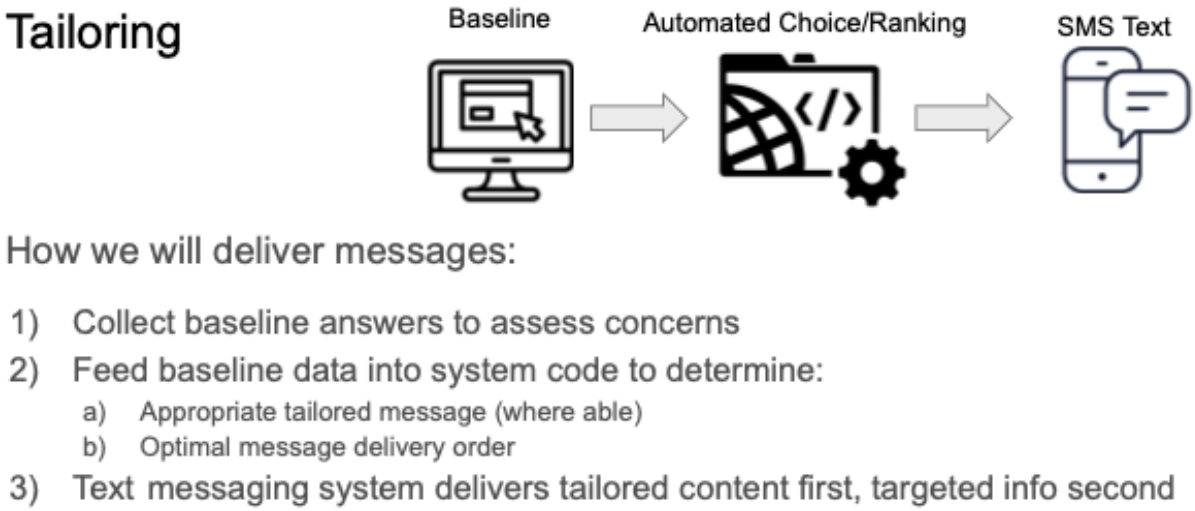
text and media (photos, graphics, animations, audio, video) delivered via a range of channels. Because of the common technical platform, resulting in tailored programs are easier to disseminate.

Theoretical Framework.

Our primary framework that will guide the web content is Self-Determination Theory (SDT). SDT differentiates between autonomous and controlled behavioral regulation. Behaviors are autonomous when they result from conscious choice and are personally relevant. Conversely, behaviors are considered controlled when performed due to pressure or coercion, either by external or internal forces. A key principle of SDT is that messages that enhance autonomy and perceived competence and are consistent with a person's values and goals will be more effective in changing behavior than messages focusing on external rewards such as pleasing others, fear of disease, or avoiding guilt, anxiety, or shame. To link vaccination to broader values and goals, in the baseline assessment, participants will be presented with approximately 20 values/life goals, from which they will select 3-4 goals that are important to them; individually tailored messages will link each of these values to vaccination. For example, if an individual chooses family or strength as key values, we will provide messages that link vaccination to being there for their family or to remain independent. We will also tailor testimonials based on member values and communication style preference (see below). Another component of autonomy that is relevant here is providing choice as to how much and what information participants receive.

Individual-Level Tailoring Message Content.

CHCR will tailor the content based on key determinants of vaccine behavior including knowledge, barriers, benefits/drivers, cultural values, mistrust, ethnic identity, communication preferences, and the personal meaning of vaccination. The final list for tailoring content will be determined by our Aim 1 formative research, preliminary data collected as part of our C3 study, and analysis of other sources. The CIVIC SC will play a critical role in reviewing these materials and deciding on the final list of content for tailoring. The mobile-optimized website will include a brief assessment of these constructs, generally using measures we have already developed. Using other methods such as testimonials, we will deliver individualized content addressing each of these constructs. For example, for someone who reports they are worried about contracting the virus from the vaccine, we will offer them what we call "essential facts" about the topic and then provide "drill down" options if they want to learn more. We will also tailor messages to drivers that we know are primary for the COVID-19 vaccine: communal responsibility and individual choice/personal health protection. For example, for someone high on communal responsibility, we will reflect this back to them in their message as "… if you got vaccinated, you would feel you are protecting others in your community…" or "… how will you feel about being a leader in your community by getting vaccinated?" Similarly, someone high on individual choice/personal health protection will be provided with feedback such as "getting the vaccine is a personal choice for you, not something you want to be shamed or pressured into doing." Similar tailored messages will be developed for each of the target mediators.



AAs are heterogeneous with regard to racial identity and this variability should be considered when designing health messages and programs for AAs. We have demonstrated that for AAs whose racial identity is central to their overall identity, messages that refer to or link race to the target behavior can be highly salient. However, for AAs with low racial centrality, framing messages around race can be poorly received or even harmful. Thus, we will use our brief message of racial centrality, based on the work of Sellers, to classify individuals by their ethnic identity and deliver messages differentially framed on respondents' identity. For example, for those with high racial centrality, we would frame their message as "… getting the vaccine can help protect other AAs from getting COVID" or "AAs have a higher rate of COVID than other Americans." For those with low racial salience, we would frame the message as "… getting the vaccine can help protect other Americans from getting COVID" or "Americans have a higher rate of COVID than other countries."

Individual-Level Tailoring Message Tone.

In several prior studies, we found that message tone impacts uptake. We have developed a tailoring algorithm that optimizes message tone based on communication preference. We assess preference with two items, one assessing the global trait preference and the other assessing preferences related to vaccine uptake. The trait item will be: "In general, when it comes to my health I would rather an expert just tell me what I should do." The state item will be: "When it comes to getting a COVID-19 vaccine I would rather an expert just tell me what I should do".

The two preference styles, which we call PUSH (directive) and PULL (autonomy-supportive), receive different tone, language, and content. The PULL tone uses more tentative and autonomy-supported language, whereas the PUSH tone is more definite and directive. Specifically, individuals preferring the PUSH style will be provided with directive advice describing what they "should do" regarding COVID-19 vaccination. Individuals preferring the more autonomy-supportive PULL tone will receive more tentative language such as "might" or "can," using questions (e.g., "How might you feel about getting the vaccine?" versus "You will feel good about yourself if you get the vaccine") and suggestions more than commands, helping them find personal meaning to make a vaccination decision.

App Usage

Champions are vaccinated persons from participating counties, who agree to consent to the study, and receive Motivational Interviewing Training to communicate with community members about their motivators and barriers to receiving the COVID-19 vaccine. Champions may join the study as vaccinated persons, or if previously enrolled as an unvaccinated participant, can become a Champion once vaccinated.

4.2 Scientific Rationale for Study Design

Aims 2 and 3 uses an individually randomized design spanning 6-months. This greatly improves the feasibility of the study as our community partners strongly encouraged us to allow all participants to receive the social marketing and Champions interventions without much delay.

Secondary outcomes include Vaccine Intentions, a continuous variable.

Participants who were unvaccinated or unboosted at will receive the intervention after completing follow-up at six months. This cohort will be followed until they are vaccinated or until the end of the study, six-months after follow-up of the primary intervention.

4.3 Justification for Dose

1 vaccine from baseline survey

4.4 End of Study Definition

At the end of the intervention period following the completion of follow-up survey. PHI will be stripped, data will be deidentified.

5 STUDY POPULATION

5.1 Inclusion Criteria

Eligibility inclusion criteria:
- unvaccinated and unboosted adults 18 years and older who are interested in participating in the study
- Must be able to read and write in English or Spanish
- Must be able to receive SMS/MMS/text messages

5.2 Exclusion Criteria

Exclusion criteria:
- Persons under the age of 18
- unable to read or write English or Spanish
- unable or unwilling to receive SMS/MMS
- unwilling to consent
- for vaccine champions-unwillingness to complete communication trainings in English

No specific racial, ethnic, nor gender group is excluded.

5.3 Lifestyle Considerations

Not applicable.

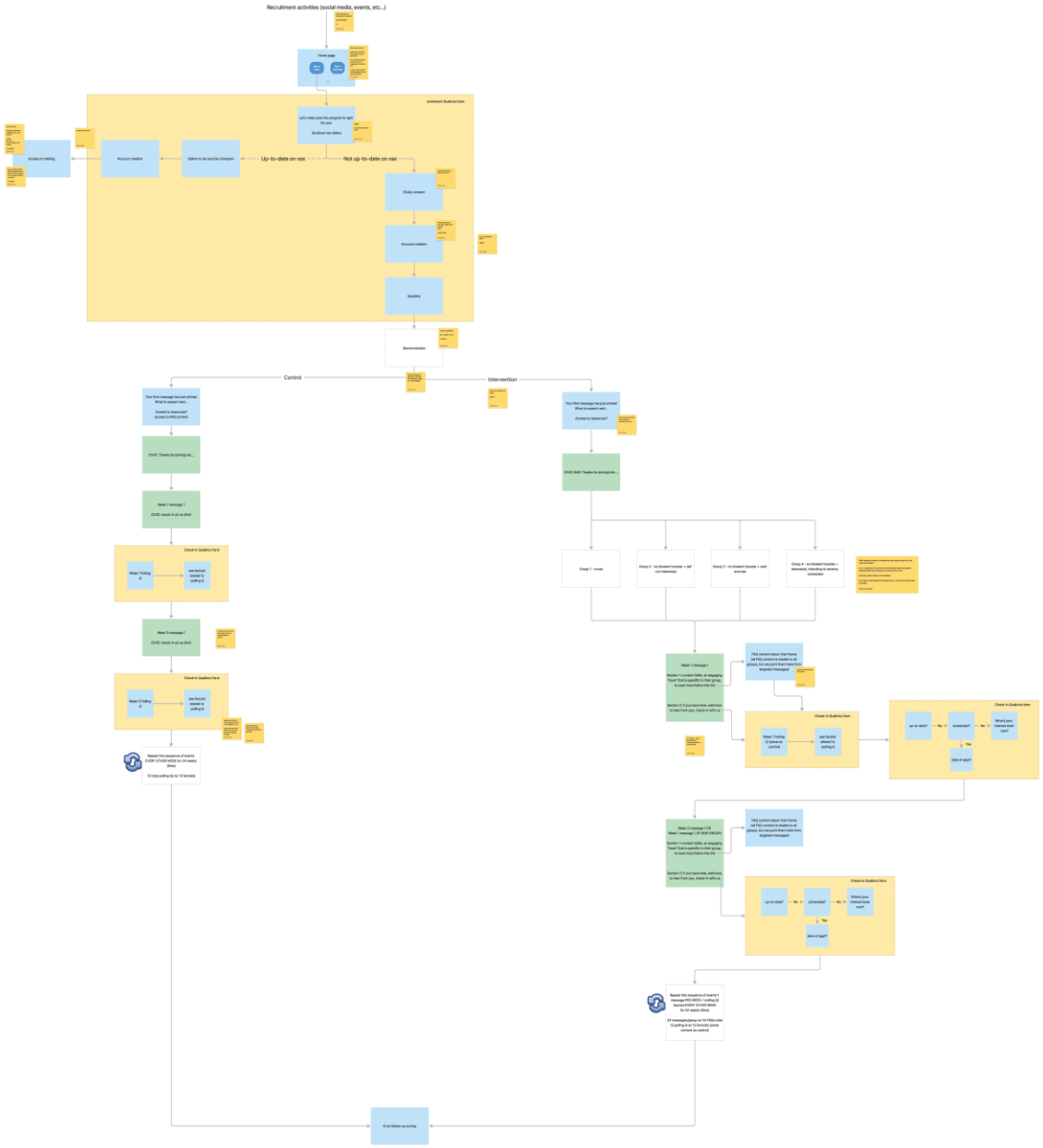
5.4 Screen Failures

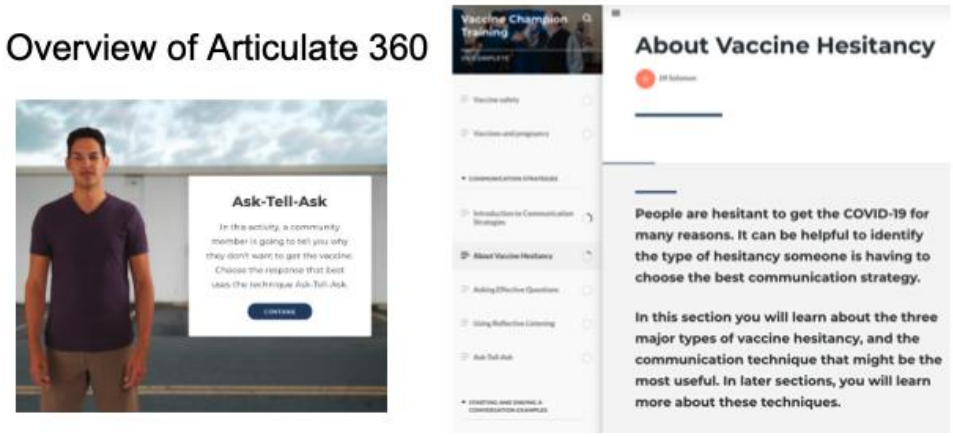
- Persons under the age of 18
- unable to read or write English or Spanish
- unable or unwilling to receive SMS/MMS
- unwilling to consent
-for vaccine champions-unwillingness/unable to complete communication trainings in English

5.5 Strategies for Recruitment and Retention of Participants

1) Change in recruitment procedures or documentation.
   a. Recruitment will be expanded to allow all Michiganders to enroll.
   b. In addition to recruiting from churches, we will expand enrollment to public events and forums such as attending health fairs, community baby showers, farmers markets, bus stops, social media, online blogs, etc.
   c. After Ame00138260, Recruitment expanded to include Data Direct
      i. Individuals meeting eligibility criteria from DataDirect will be contacted by phone, up to 8 times over a 6-week period. Recruiters will use the script in "8.1-6_AME00138260_HUM00204174_Data-Direct-Recruitment-Script_English.pdf(0.01)" or "8.1-6_AME00138260_HUM00204174_Data-Direct-Recruitment-Script_Spanish.pdf(0.01)" as appropriate. Individuals will be contacted by IRB-approved study team members from the study's phone # (734) 615-2860. Individuals identified as meeting eligibility criteria from DataDirect will be included in a file sent securely to the G2YMI study team. File data elements include name, phone, email. While vaccination status is not included in the file, only individuals who are not currently up-to-date, according to their MiChart EMR, will be provided to the study team, and contacted to invite to participate.
2) If someone is interested in participating they may enroll at www.g2ymi.org ("the website"). The electronic survey and responses are stored on secure servers. They may access this URL by:
   a. type "the website" into an internet browser or
   b. request a link to "the website" be sent to them via SMS (data and service charges may apply depending on a person's phone carrier and plan)
   c. receive the link in their secured inbox in their U-M Health Research account
   d. Receive the link by phone.

Newly Enrolled (post December 2022) Vaccine Champions will complete the virtual, MI-based, (Articulate) communications training only. No incentive will be paid to newly enrolled Vaccine Champions. Note: Currently enrolled (prior to December 2022) Vaccine Champion Plus will be trained on motivational interviewing and COVID-19 vaccine facts. They will receive abbreviated PEERRS training as well as Motivational Interviewing techniques. We will distribute vaccine champions initial $50 payment after a self-paced virtual and $50 for a live-virtual MI-based communication training.


Recruitment activities (social media, events, etc...)
Home page
Let's make sure this program is right for you
Go direct non status
Access to mailing
Account creation
Option to be vaccine champion
Up-to-date on vax
Not up-to-date on vax
Study consent
Account creation
Baseline
Randomization
Control
Intervention
Week 1 message 1
Week 2 message 1
Week 3 Polling Q
see factoid related to polling Q
Week 3 message 1
Week 4 Polling Q
see factoid related to polling Q
Repeat this sequence of events EVERY OTHER WEEK for 24 weeks (6mo)
Week 1 message 1
Week 1 Polling Q (same as control)
see factoid related to polling Q
Week 2 message 1 OR
Week 1 message 1 BY WEEK GROUP!
Repeat this sequence of events EVERY OTHER WEEK (EOW) for total 12 polling Q's w/ 12 factoids (6mo)
24 messages/group w/ 12 FAQs total
6 mo follow-up survey



Privacy is critical to the study team and steps to maintain confidentiality of research subjects is described in Section 6 of this application.

Neither participant information, nor consent/enrollment status, will not be shared with any participants' healthcare providers.

P.I. Dr. Ken Resnicow and Co-I Pastor Williams meets with RSL from the four intervention counties, who meet on a monthly basis, and will decrease as the study continues. All RSL from the counties are invited and encouraged to attend the meetings, along with study team members. These meetings are currently virtual.

6 STUDY INTERVENTION

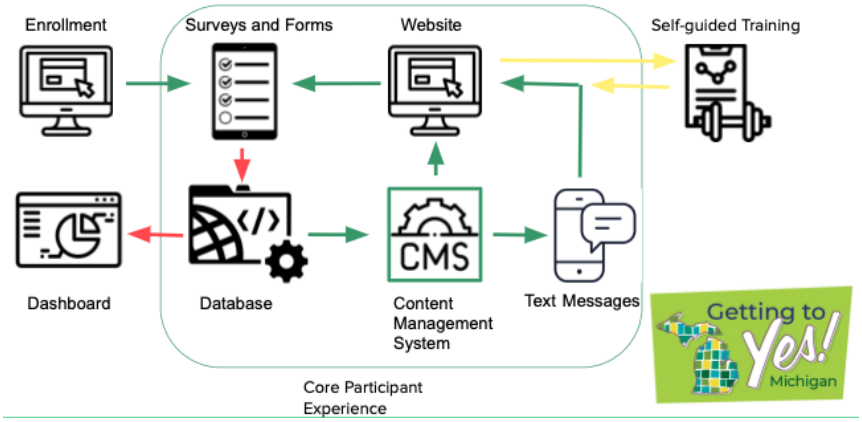
6.1 Study Intervention(s) Administration

MI Training for Champions the digital version can be found here.
https://360.articulate.com/review/content/1b8f6140-026e-4ee8-91b7-419bdc3cf7c3/review
SMS/MMS Intervention

Human Subjects Training for Vaccine Champions the digital version can be found here.
https://docs.google.com/presentation/d/1t2SD4gAPkggBPTwRbByaXxPVKoPDt2NsbAWnPEiT8gA/edit?usp=sharing

6.2 Preparation/Handling/Storage/Accountability

6.2.1 Acquisition and accountability



6.2.2 Formulation, Appearance, Packaging, and Labeling

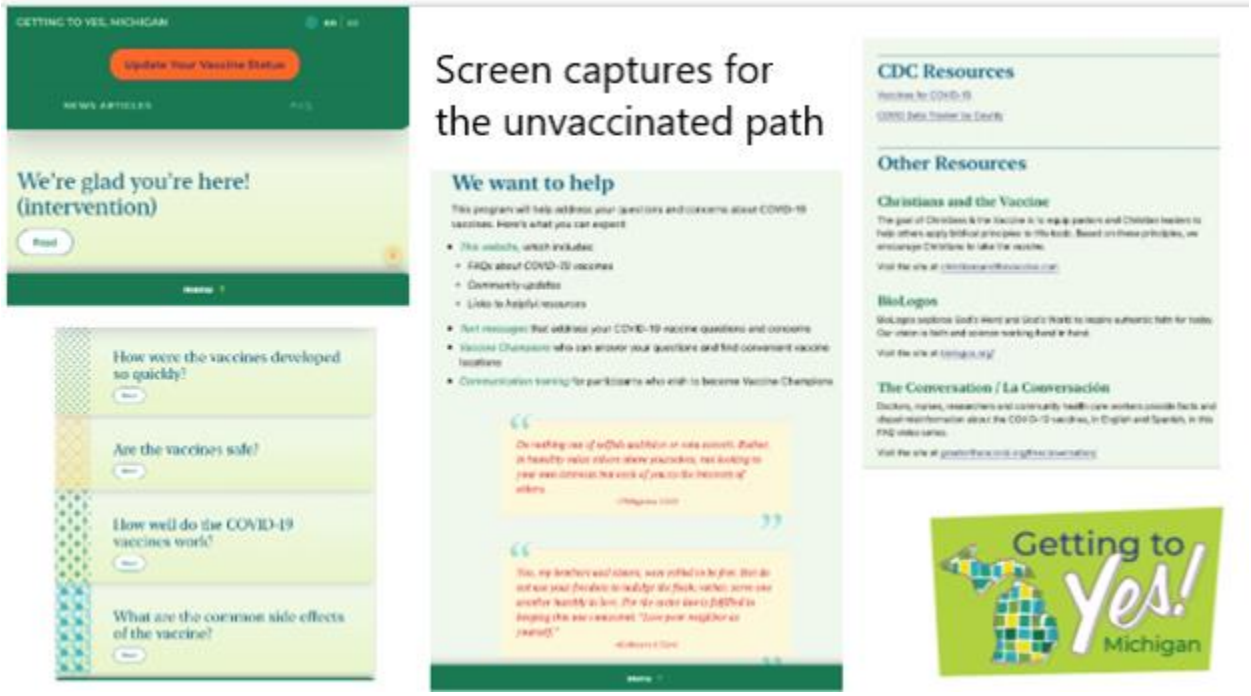
The Participant Experience: Website

The participant will go to www.g2ymi.org to enroll in the program

Their view of the website will vary based on data captured during enrollment:

- Vaccination Status
- Control vs. Intervention Status
- Content created for churches/communities (if applicable)

Getting to Yes! Michigan



6.2.3 Product Storage and Stability

Not applicable

6.2.4 Preparation

Not applicable

6.3 Measures to Minimize Bias: Randomization and Blinding

Using an individual-randomized design and working through the same churches (AA only) that participated in the Aim 2 multilevel intervention, we will develop and test, with the active engagement of the CIVIC SC, the impact of a tailored mobile-optimized web intervention on vaccine uptake. Individually tailored interventions have consistently been shown to be more efficacious than group-level or static messages. Participants, none of whom will have been vaccinated, will be randomly assigned to each condition.

6.4 Study Intervention Compliance

We are not anticipating any AE's. We are collecting limited data from subjects. Routine study monitoring by the PMs and technology staff at CHCR, could identify a reportable event, such as concerns following the approved protocol, IRB application, or agreements with the NIH and this award. Unexpected adverse events (i.e., has NOT been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSC Reports, published literature, other documentation)

6.5 Concomitant Therapy

Not applicable.

6.5.1 Rescue Medicine

Not applicable.

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Discontinuation of Study Intervention

Previously collected data will remain intact, until the end of the intervention collection period when it's deidentified. No further contact or data collection will occur.

7.2 Participant Discontinuation/Withdrawal from the Study

While the study team does not anticipate the need to end a subject's participation, nor a Champion's participation, they will routinely monitor and review the study for adverse events (AE) or other reportable events such as protocol deviations (ORIO). Unexpected, clinically significant, findings will be reported as an AE/ORIO with this application.

Should a participate request withdraw, the study team member will follow-up with the participant, unless requested not to be contacted, to assess a possible reportable event.

If a Champion is found to disseminate information in contradiction to the information provided with their MI training or the CDC recommendations, they may be corrected and offered an opportunity for improvement or be asked to stop their participation.

7.3 Lost to Follow-Up

Participants who have not been reached for at least 8-weeks after enrollment, or about 10 times for recruitment, will be considered lost to follow-up. Participants may resume the intervention at the point they left off.,

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 Efficacy Assessments

Eligibility:

- unvaccinated/unboosted adults 18 years and older who are interested in participating in the study
- Must be able to read English or Spanish
- Must be able to receive SMS/MMS/text messages

Screening: Community members who text to enroll will receive an SMS/MMS with a link to complete eligibility screening and consent.

- Unvaccinated/unboosted enrollees may enroll in the SMS/MMS intervention.
- Fully Vaccinated individuals may become Vaccine Champions for their community. Prior to December 2022, those that are enrolled will become Vaccine Champion Plus and were primarily recruited through the collaborating churches. VC+ will complete the Motivational Interviewing (MI) Training, which provides evidence-based methods to communicate about motivators and barriers to health interventions, over Zoom, if in-person activities are not permitted at the time of the training. At the MI Training, Champions will be informed of how to assess when the person might need follow-up to discuss their barriers and motivators for the vaccine. VC+'s will be manually matched to participants by the study team. They will have access to identifiable information through the G2YMI dashboard under the vaccine champion permissions on G2YMI.

-After January 2022, fully vaccinated individuals can become vaccine champions. They will not interact with participants. The champions can complete the Motivational Interviewing training on the Articulate 360 platform.

Recruitment and study procedures:

RSL will agree to recruit their church attendees by completing the via one church-wide announcement using the communication method preferred by their congregation (i.e face-to-face, phone, email) using the Key Facts Script that includes the URL and QR code to the Eligibility Screener and Consent.

We will also work with the CIVIC Steering Committee (SC) for recruitment of individuals in the four focal communities. The SC is made up of community leaders from across Wayne, Washtenaw, Genesee and Kent counties.

Previous to the RCT change, we enrolled church RSL who expressed interest in participating by completing the survey located in 10-1.6 Church-Eligibility-Survey_HUM00206580. Recipients of the survey will be encouraged to distribute the survey to their own networks to reach the eligible churches. We will continue to work with the RSL and staff from our 32 collaborating churches.

- Survey data collection is done using Qualtrics (baseline, check-in, 6mo follow-up). We use the instance of Qualtrics under the UM license which is approved for collection of sensitive data.
- Electronic signatures are obtained for CIA and PPA forms using SignNow.

Potential Enrollees who text to enroll will receive an SMS/MMS with a link to complete eligibility screening and consent.

- SMS/MMS are sent via Twilio.
- Unvaccinated/unboosted enrollees may enroll in the SMS/MMS intervention
- Vaccinated enrollees
    - Enrolled prior to Dec 2022, may become vaccine Champions for their community. Champions will complete the Motivational Interviewing (MI) Training, which provides evidence-based methods to communicate about motivators and barriers to health interventions, over Zoom, if in-person activities are not permitted at the time of the training. At the MI Training, Champions will be informed of how to assess when the person might need follow-up to discuss their barriers and motivators for the vaccine. Human subjects in research training will also be provided.
    - Enrolled after Dec 2022, may complete the MI (Articulate) online training to aid conversations around vaccine hesitancy but will not interact with participants.

We will be recruiting people at community events and locations such as health fairs and bus stops. We will also utilize social media in our recruitment efforts. We will be using face-to-face communications, scripts (attached) and other recruitment materials such as flyers, posters, business cards.

Recruitment of those from Data Direct will contact individuals using IRB-approved phone scripts (attached in eResearch 08-1).

8.2 Safety and Other Assessments

A Data Safety Committee (DSC) will be put into place as an integral part of the study's manual of procedures—to monitor participant safety and evaluate the ability of the investigators to conduct the proposed study with utmost regard for participant, Champion, and church protection and confidentiality. The study will not begin without approvals of the University of Michigan IRB. The PI and study team will conduct periodic reviews of regulatory requirements.

In addition, in accordance with federal regulations, the Data Safety Committee will convene to act in an advisory capacity to the study and NIH NIDDK to monitor patient safety and evaluate the ability of the investigators to conduct the proposed research with utmost regard for patient protection and confidentiality. The DSC will undertake the following tasks:

1. Approve initiation of the proposed study prior to study enrollment.
2. Review the research protocol, informed consent documents, and plans for data safety and monitoring.

3. Evaluate the progress of the study including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the clinical centers, and other factors that may affect study outcomes. This will occur on an ongoing basis.

4. Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.

5. Protect the safety of the study participants.

6. Report on the safety and progress of the study.

7. Make recommendations to the study team and NIH HHS, and if required, to the IRBs concerning continuation, termination or other modifications of the study based on the observed beneficial or adverse effects of the study procedures.

8. Review interim analysis in accordance with stopping rules that will be developed for the study protocol and that will be defined in advance of data analysis and have approval of the DSC.

9. Ensure the confidentiality of the study data and the results of monitoring.

10. Assist the funding agency by commenting on any problems of study conduct, enrollment, sample size, and/or data collection.

All aspects of the proposed research will be conducted with utmost regard for the welfare and privacy of the volunteer participants. The DSC meetings shall be closed to the public because discussions may address confidential patient data. Urgent or emergent meetings of the DSC may be called at any time or in the event of issues regarding patient safety. The format for the DSC meetings may be open or closed as dictated by the agenda of the meeting.

Termination of the Study: A majority vote of the DSC will be required to issue a study termination recommendation. Potential reasons could be but are not limited to:

1. An exceedingly large number of serious and unexpected adverse events.
2. Severe and not rectifiable logistical or data quality problems.

The DSC will consist of study team members who include a clinical leader and well-established researcher, PMs, Research Assistants, and the PI. The study biostatistician will be available to provide input and/or attend the DSC meetings, as needed.

In addition, any data integrity and patient safety-related issues will be prioritized. At study start, all research personnel, coaches and staff will undergo training and in-service meetings about study procedures. The importance of data security and compliance with procedures will be emphasized. All study personnel are required to complete and be certified by the Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) at the University of Michigan every 3 years (or equivalent, i.e. CITI training as applicable depending on University/site affiliation). A standard reporting form for adverse events will be created and completed by study personnel on an as-needed basis. Adverse events will be discussed at biweekly team meetings or sooner if needed and reported to the IRB. Documentation of completion of tasks and DSC activities will available in the team meeting minutes and ORIO/AEs submitted to the IRB.

A Regulatory and Compliance Dropbox folder will also contain all communications to the IRB, including the initial application, study protocol, any amendments, annual IRB renewal, IRB approvals, and a summary of adverse events. It will be the responsibility of the project team to maintain and update the folder. In addition, the Project Manager/Coordinator will review consent forms, and source data at regular intervals along the study, with reviews documented in a Monitoring Log, accompanied by a Monitoring Report, which will be filed in the Regulatory Binder.

Lastly, this project includes an applicable clinical trial registered with ClinicalTrials.gov, NCT#05096260.

8.3 Adverse Events and Serious Adverse Events

8.3.1 Definition of Adverse Events (AE)

According to the UM Medical School Office of Research definition, an adverse event (AE) is any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio.

8.3.2 Definition of Serious Adverse Events (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

8.3.3 Classification of an Adverse Event

1.1.1.1 Severity of Event

According to the UM eResearch definition, adverse events are categorized according to the following grading system:

0 - No adverse event
1 - Mild AE – No treatment needed
2 - Moderate AE – Resolved with treatment
3 - Severe AE – Inability to carry on normal activities, required professional medical attention
4 - Life-threatening or disabling AE
5 - Fatal AE

1.1.1.2 Relationship to Study INTERVENTION

We will use the following levels of relationship to study intervention, which is in accordance to eResearch:

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, occurs in a plausible time relationship to study intervention administration and cannot be explained by concurrent disease or other

drugs or chemicals. The response to withdrawal of the study intervention (dechallenge) should be clinically plausible.

- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event occurs within a reasonable time after administration of the study intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals.
- **Possibly Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial medication). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study intervention) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology.

1.1.1.3 Expectedness

The principal investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

- Psychosocial difficulties
    - Potential expected and unexpected risks will be outlined for patients in the informed consent document(s).
- Potential Benefits
    - There are no immediate health benefits to the study subjects. This study, however, will provide important information about the beliefs, behaviors, sources of truth, and misinformation that drive COVID-19 vaccine uptake so that in the future others might benefit from this study. The risks of the study are considered minimal.
- Potential Risks
    - Likelihood: There is the "rare" potential risk that participants may be embarrassed or upset by questions in the questionnaires or interviews.
    - Seriousness: We anticipant <1% risk as subjects will have the option to not answer any questions that they determine to be too sensitive. Questions have been previewed by community members, religious and spiritual leaders, and items deemed too sensitive were removed from the intervention, and not listed in this application.
    - Measures to minimize risk: Privacy is very important, and the study investigators will use many safety measures to protect subject privacy.
    - Participation in this research is voluntary, and they may choose to withdraw at any time by contacting the study team at *gettingtoyesmi@med.umich.edu*
    - Participation in this research is confidential. All research data will be de-identified, and subjects will be identified by number and not by name. No information by which the subject can be identified will be released or published in connection with this study.

- No information by which the subject can be identified will be released or published in connection with this study. In spite of all of the safety measures that we will use, however, we cannot guarantee that subject identity will never become known.
- Study paper data i.e. consent forms and history forms will be stored in locked cabinets, and electronic data will be stored servers accessible via password-protected computers.
- Study data will be stored in a relational database on a separate highly restricted secure server. Databases will be backed up daily to an offsite NAS storage device using automatic backup software that is available 24/7 except for scheduled maintenance. Only the primary investigators and other authorized research team members named in this application will have access to the de-identified data. These standards will help ensure that violations of confidentiality will be minimal.
- The procedures outlined in this proposal are considered minimal risk. There are no anticipated medical risks.
- There is the potential risk that participants may be embarrassed or upset by questions in the questionnaires or interviews. Subjects will have the option to not answer any questions that they determine to be too sensitive.

The definitions from eResearch on expectedness is as follows:

- Unexpected adverse events (i.e., has NOT been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSC Reports, published literature, other documentation)
- Expected adverse events (i.e., has been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSC Reports, published literature, other documentation, or characteristics of the study population)
- *This study is minimal risk and we anticipate an increased uptake in the COVID-19 vaccine in the four target counties. This will help reduce the spread of COVID-19 virus and associated misinformation.*

1.1.2 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician’s assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

The study team will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

1.1.3 Adverse Event Reporting

We will report all adverse event according to the UM Medical School Office of Research reporting timetable:

Standard Adverse Event Reporting Guidelines for INTERNAL AEs Occurring at UM

This chart is for studies following IRBMED standard AE reporting and requiring CR. It may be appropriate for some studies to consider a Study Specific AE Reporting Plan. See the gray boxes for information about External AE and UaP reporting.

		RELATED	UNRELATED
UNEXPECTED	Potential Unanticipated Problems (UaPs)[3] Note: Some UaPs are not AEs. Report these events via an ORIO.	**Serious Adverse Event[1]** – resulting in • **Death** • **Life-threatening outcome** Submit AE/ORIO report as *soon as possible*, **but** *within 7 calendar days* of becoming aware of event. Assess SAE to determine if UaP (see below for UaP criteria).	**Serious Adverse Event[1]**- resulting in • **Death** • **Life-threatening outcome** Report in aggregate form via separate AE/ORIO submission *in conjunction with SCR*
		Serious Adverse Event[2] Submit AE/ORIO report *within 14 calendar days* of becoming aware of event. Assess SAE to determine if UaP (see below for UaP criteria).	**Serious Adverse Event[2]** Report in aggregate form via separate AE/ORIO submission *in conjunction with SCR*
		Non-Serious Adverse Event Report in aggregate form via AE/ORIO report *in conjunction with completion of the SCR*. Assess AE to determine if UaP (see below for UaP criteria).	**Non-Serious Adverse Event** **-Do not report to IRB-** Study teams should continue to monitor and log events as they occur for sponsor reporting purposes.
EXPECTED		**Serious Adverse Event[1,2]** Submit AE/ORIO report *within 14 calendar days* of becoming aware of event.	**For ALL Unrelated & Expected Adverse Events** **-Do not report to IRB-** Study teams should continue to monitor and log events as they occur. If any events appear to be occurring at a severity or frequency greater than previously known or expected, report as 'unexpected' per these guidelines *within 14 calendar days* of identifying this trend.
		Non-Serious Adverse Event (Moderate/Grade 2*) **-Do not report to IRB-** Study teams should continue to monitor and log events as they occur. If any events appear to be occurring at a frequency greater than previously known or expected, report as unexpected *within 14 calendar days* of identifying trend.	
		Non-Serious Adverse Event (Mild/Grade 1*) **-Do not report to IRB-** Study teams should continue to monitor and log events as they occur. If any events appear to be occurring at a frequency greater than previously known or expected, report as unexpected *within 14 calendar days* of identifying trend.	

1.1.4 Serious Adverse Event Reporting

We will report serious adverse events according to the Office of Research timetable above. DSC described in section 8.2. We do not anticipate any study-related serious adverse events to occur as this is a study with no more than minimal risk.

1.1.5 Reporting Events to Participants

Not applicable – Any adverse events that may happen will likely be due to individual differences, e.g. baseline mental and physical health status, instead of systemic issues.

1.1.6 Reporting of Pregnancy

N/A

1.2 Unanticipated Problems

1.2.1 Definition of Unanticipated Problems (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

1.2.2 Unanticipated Problem Reporting

According to UM Medical School Office of Research guidelines:

Serious unanticipated problems and Unanticipated Adverse Device Effects (UADEs) must be reported within 7 calendar days of the problem (or within 7 calendar days of the study team becoming aware of the problem). Non-serious unanticipated problems must be reported within 14 calendar days of the problem (or within 14 calendar days of the study team becoming aware of the problem).

If the unanticipated problem involved one or more persons experiencing actual harm, report the unanticipated problem as an adverse event. Refer to the AE Reporting page (*https://az.research.umich.edu/medschool/guidance/adverse-event-reporting*) and follow the instructions provided, using the external or internal form as appropriate.

If a person did not experience actual harm but an unanticipated problem entailed potential harm, and/or risk of harm to subjects or others, refer to the ORIO Reporting page (*https://az.research.umich.edu/medschool/guidance/other-reportable-information-or-occurrence-orio*) and follow the instructions provided.

If the IRB concurs that an event is an unanticipated problem the study team will follow the policies and procedures outlined in the University of Michigan Human Research Protection Plan Operations Manual, part 12.

1.2.3 Reporting Unanticipated Problems to Participants

N/A

2 STATISTICAL CONSIDERATIONS

2.1 Study Hypotheses

To increase the uptake of COVID-19 vaccinations amongst African American/Black and Latinx persons living in the counties of Washtenaw, Kent, Wayne, and Genesee.

1: Increase understanding of the barriers and drivers of vaccine uptake and hesitancy;
2: Increase vaccine uptake and decrease vaccine hesitancy through the implementation and evaluation of a multilevel intervention; and maintain, enhance, and evaluate the effectiveness of the CIVIC partnership to equitably engage all partners.

2.2 Sample Size Determination

PIs Resnicow and Spino have calculated sample size to account for power and individually randomized control trial.

2.3 Populations for Analyses

Individuals enrolled in the study will be from predominately African American/Black and Latinx populations.

2.4 Statistical Analyses

2.4.1 General Approach

We will follow international guidelines for analysis and reporting of individually randomized clinical trials. We will first examine the distributions of all study variables to assess missing data, possible coding errors, and distributional form, including skewness, variance, and extreme values.

Participants will see a public "**control**" **website** until their group changes into Intervention.
**While the enrollment period is open throughout the intervention, only those who complete the baseline prior to the first bi-monthly check-in will have a tailored text message experience.

2.4.2 Analysis of the Primary Efficacy Endpoint(s)

For the primary outcome (vaccine uptake), All data will be de-identified to ensure confidentiality of participants, with results presented in summary to protect confidentiality. Analysis of quantitative questionnaire data will involve descriptive statistics, comparison of years 1-5, and examination by partner role (community or academic). Given the small number of SC members (n=19), statistical tests of significance will not be used; rather, we will identify trends for further discussion. We will use a systematic process of coding and constant comparison of all qualitative data to conceptualize group content[127] and to consider similarities and differences in responses for different groups (e.g., academic, community). Key quotes from the qualitative data will be selected to illustrate themes.

Descriptive statistics will be tabulated and graphical methods will be used to characterize individuals and churches. In Aim 2, summaries over time also provides information on intervention status to allow consideration of selection biases and balance. An intention-to-treat approach will be used to define the

analysis population: all participants enrolled in each randomized church for Aim 2 will be analyzed. We will summarize the extent of missing data over time for the primary endpoints. Differences in participant demographics and baseline characteristics between those with and without missing follow-up data will be given overall and by intervention group. Two-sided p-value will be reported and no adjustments for multiplicity will be made. Thus, p-values for secondary and exploratory outcomes will be interpreted with caution. Confidence intervals will be provided to summarize differences between interventions. A statistical analysis plan will be finalized prior to locking the databases. The primary outcome is the binary variable of patient reported vaccine uptake over the 6 month assessment period of the stepped wedge. Analyses will use a generalized linear mixed model with a logit link to account for the binary primary outcome; vaccinated (YES/NO). The model addresses the stepped-wedge design features including adjusting for calendar time as a fixed effect (time period) and an indicator variable that describes the treatment in each cluster (church) at each time. Given the cluster randomized nature and cohort follow-up in our stepped-wedge design, we will include a random intercept to account for church clustering (ICC) and a random effect for individuals in the model. An exchangeable correlation matrix that assumes similar correlation between outcomes for participants within the same church will be used. The primary statistic of interest is in the odds of vaccination between the intervention and waiting conditions, controlling for church level clustering (ICC) as well as individual level covariates, e.g., age, gender, income, education, all of which have been shown to influence vaccine uptake. Relationships between the demographics and outcome variables will be examined in bivariate analyses (Pearson and Spearman correlations, t-tests, and χ_2-tests). The selection of appropriate covariates for multivariable analyses will follow the variable selection approach of Heinze et al[15,16] that incorporates background knowledge as well as statistical criteria (such as significance of covariates with $p < 0.05$ or Akaike information criterion). Continuous variables such as our secondary outcome, i.e., intentions to vaccinate, will be analyzed similarly, using the identity link and the normal distribution. A priori interaction terms (intervention effect modifiers) that will be test include gender, income, education, church denomination, and ethnic identity. We will also test time interactions with treatment condition. This will allow us to determine if different lengths of exposure to the intervention yield greater outcomes, i.e., dose response effects. We expect missingness of vaccine data to be modest (< 20%), and our models account for any missingness at random. If there is substantial missingness or missingness not at random, we will use the most advanced missing data handling methods (e.g., multiple group multiple imputation) to maintain sample size and methods such as selection and pattern mixture modeling[17]. Sensitivity analyses for each Aim's primary endpoint will be performed to assess the impact of missingness assumptions and approach on study conclusions.

Mediation Analyses.

We will use mediation analyses [18 19,20-22] under the direction of Drs. Resnicow and Spino to examine whether intervention effects on vaccine uptake and vaccine intentions, if observed, can be explained by changes in key psychosocial variables. Similar analyses will be conducted for the Aim 2 study. Specifically, we will examine whether changes in intervention targets such as vaccine attitudes, vaccine barriers, vaccine confidence, autonomous motivation, social norms, etc. account for intervention effects. Full mediation, a rare phenomenon, occurs when the association between treatment and outcome is fully eliminated in regression analyses. Mediation will be tested in a three-step process.[21] First, the mediator must be affected by the independent variable (IV) of intervention. Second, the intervention must be shown to affect outcomes. Finally, it must be shown that when the dependent variable is regressed on both the independent and mediator(s), the association between IV and outcomes is attenuated. We will estimate the direct and indirect effects of the mediating variables on primary outcomes and the structural relationships (or paths) linking them using the causal inference approaches to measure the direct and effects[22-24]. In addition to the regression approach, we will also

use structural equation modeling (SEM) to test and visualize mediation effects. We will examine the mediators using the R package lavaan to determine indirect effects using bootstrapping. Bootstrapping does not assume normality of the product term used to examine indirect effects. Moreover, lavaan can use full information maximum likelihood estimation to efficiently address any missing data that is either missing completely at random or missing at random in any of these constructs. Finally, we will explore whether improvements in primary outcomes are associated with different exposures such as time in the social marketing intervention or number of Champion contacts.

2.4.3 Analysis of the Secondary Endpoint(s)

Vaccine intentions will be assessed by asking, on a scale of 0-10, “how likely is it that you will get the COVID-19 vaccine?”, with 0 being very unlikely and 10 being very likely. This will be analyzed using linear regression as described in the data analysis section. "

2.4.4 Safety and Interim Analyses

Safety monitoring, classification of events and reporting are described in section 8. While there are no planned interim analyses other than what is done for study data safety along enrollment for the study, we may begin analysis sooner.

- The DSC members will review the following on an ongoing basis. Number screened, number enrolled, number withdrawn.
- Demographics for patients enrolled in control and intervention clinics.
- Adverse events analysis which will include descriptive analyses of the adverse event, severity, whether unexpected or expected, whether or not there were associated hospitalizations.

2.4.5 Baseline Descriptive Statistics

2.4.6 Tabulation of Individual Participant Data

Individual participant data will not be listed by measure and time point except for safety monitoring and reporting to IRB— and then only as aggregate and not identifiable, as outlined in section 8.

2.4.7 Exploratory Analyses

3 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

3.1 Regulatory, Ethical, and Study Oversight Considerations

3.1.1 Informed Consent Process

This study protocol will not be implemented until reviewed and approved by the University of Michigan IRB. Potential subjects who approach study staff in person, via phone, in writing or via email, will be contacted by study staff, informed about the study and presented with the option to participate. Informed consent will be obtained prior to participation by study staff. Subjects will be informed in all cases about their rights as research subjects. Their participation is voluntary. They may decline participation without penalty or loss of any healthcare benefit or service to which they are entitled. All recruiting site personnel convey this information through the written and verbal consent process.

3.1.1.1 Consent/assent and Other Informational Documents Provided to participants

Consent will be obtained through the study website. Instead of a signature, they will be asked if they agree to be in the study. Answering "yes" to that question indicates consent to enroll in the study. The consent form describes in detail the study intervention, study procedures, risks and benefits, and contact information for the study team. Copy of the consent forms (one for patients enrolled to serve as controls and other for patients enrolled to receive intervention) are uploaded in eResearch.

3.1.1.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. The consent process will be completed electronically through the study website.

The participant will sign/say yes to and complete the informed consent process prior to any procedures being done specifically for this study and activities that are not unregulated. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without negative impact to them (without prejudice). An electronic copy of the informed consent document will be given or sent to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be emphasized and consent will include a specific statement that the quality of their medical care will not be adversely affected if they decline to participate in this study.

3.1.2 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities as appropriate. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor, DSC and IRB.

3.1.3 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover testing of biological samples, patient-reported measures (either during coaches or study surveys) and clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. In this case the clinical study site will permit access to such records.

The study participant's contact information will be securely stored on a secure server at U-M for as long a period as dictated by the reviewing IRB, institutional policies, or sponsor requirements.

The database that contains survey results and clinical data will only be identified by study ID's. A separate file will be created to link the participant's name and other identifiable data to the study ID. Only the core study team (e.g. PI and research assistants) will have access to the password protected linking file. We do not anticipate any information to be identifiable without the linking file. Only key personnel will be able to have access to identifiable information on participants.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the University of Michigan. All transferred data will abide by local and UM policies regarding sharing data and encryption. The study data entry and study management systems used by clinical sites and by University of Michigan research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the University of Michigan.

Certificate of Confidentiality

To further protect the privacy of study participants, a Certificate of Confidentiality will be issued by the National Institutes of Health (NIH). This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

3.1.4 Future Use of Stored Specimens and Data

- Deidentified data will be retained for study record keeping purposes and future research, it will be stored, indefinitely, on secure servers at U-M.
- Data will be stripped of all identifiers before storage.

3.1.5 Key Roles and Study Governance

Principle Investigator:

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3.1.6 Safety Oversight

Safety oversight will be under the direction of a Data and Safety Committee (DSC) composed of individuals with the appropriate expertise. The DSC will consist of selected members who have no conflicts of interest with the study. The DSC will be led by the PI. He has served on other DSCs and is both a clinical leader and well-established researcher. As needed, the PI and study biostatistician will be available to provide input and attend the DSC meetings. The DSC has approved initiation of the proposed study for enrollment of human subjects, evaluate the progress of the study at initiation, when enrollment is 25% complete, 50% complete, and 100% complete. Additionally, if the study is slow to recruit, the DSC will meet at least yearly. In addition, urgent or emergent meetings of the DSC may be called at any time by the chair of the DSC or NIH project officer in event of any issues regarding patient safety. At this time, each data element that the DSC needs to assess will be clearly defined. DSC reports will be included in status reports (RPPR reporting) to the NIH yearly.

3.1.7 Clinical Monitoring

N/a

3.1.8 Quality Assurance and Quality Control

To ensure consistent delivery of the intervention and uniform application of enrollment and data collection protocols, we hosted a kick-off meeting in Year 1 attended by prospective Religious and Spiritual Leaders, research staff, project support and Steering Committee members. Goals of the study were discussed along with design and procedures. Study team members have been split into teams and assigned aspects of the study to develop and give input on study materials development. In addition, we brought in experts in quality improvement (through UM Quality and Innovation Program) and leaders on the study team in continuous quality improvement (CQI). With study team member input, we have developed a study team communication plan for study personnel, staff, co-investigators, as well as providers and staff in involved clinics. We are working with staff at UM to develop an online project website, and there will be an additional secure/password protected feature for providers from involved clinics to sign in and learn more about the study. Descriptions of the study will be produced in a variety of formats for distribution via group emails and as handouts in the community that include study key facts for consistency.

In addition, for specific study procedures, we will produce data collection manuals with detailed instructions for issues such as how to note missing data, how to make changes on data collection forms, and how to adjudicate decisions when survey response options are unclear and have this reviewed by our colleague experts in CQI. In addition, once enrollment begins, data quality issues will be discussed at weekly meetings between project staff and the PI. Data integrity and completeness will be checked periodically by research personnel and reported at biweekly team meetings as described previously in section 8.2.

Quality control (QC) procedures will be implemented beginning with the data entry systems and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to staff for clarification/resolution.

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

Rigor and reproducibility will be maximized by quality control of all study protocols and procedures and by using a robust experimental design for the intervention. This study applies high standards in its methodology and its analysis plan which will be continued through interpretation and results reporting. We will be transparent in reporting experimental details so that others may reproduce and extend the findings in the future.

3.1.9 Data Handling and Record Keeping

Data will be deidentified for indefinite storage on secured servers at U-M, to assist with future research. Study data will be stored in a relational database on a separate highly restricted secure server. Databases will be backed up daily to an offsite NAS storage device using automatic backup software that is available 24/7 except for scheduled maintenance. Only the primary investigators and other authorized research team members named in this application will have access to the de-identified data. These standards will help ensure that violations of confidentiality will be minimal.

3.1.9.1 Data Collection and Management Responsibilities

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Study data will be stored on research compliant servers provided by the University of Michigan. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

3.1.9.2 Study Records Retention

Study documents will be retained until the formal discontinuation of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

3.1.10 Protocol Deviations

It is the responsibility of the PI to use continuous vigilance to identify and report deviations. All deviations will be addressed in study source documents, reported to the NIH Program Official and University of Michigan Institutional Review Board (IRB). The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

3.1.11 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers years after the completion of the primary endpoint by contacting Ken Resnicow, Ph.D.

3.1.12 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIH and U-M that have established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

3.2 Additional Considerations

Not applicable.

3.3 Abbreviations

AA	African Americans
AE	Adverse Event
CIVIC	Community-centered Interventions for Vaccine Uptake for COVID-1(
DSC	Data Safety Committee
GCP	Good Clinical Practice
G2YMI	Getting to Yes, Michigan!
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
LX	Latinx
NCT	National Clinical Trial
NIH	National Institutes of Health
PI	Principal Investigator
RA	Research assistant / research associate
U-M	University of Michigan
UP	Unanticipated Problem
US	United States

3.4 Protocol Amendment History

Amendment #1: Ame00123018 Recruitment

1. Recruitment materials have been updated to exclude outdated language not approved in original app. These added recruitment materials for use at churches (e.g. posters, business cards, prompts for written communications from RSL to church attendees).
2. Additional churches have opted to participate and added to Participating sites.
3. Spanish consent has additional sentence added.
4. Updated study email from *gettingtoyesmichigan@umich.edu* to *gettingtoyesmi@med.umich.edu*.

Amendment #2: Ame00123968 Staff, Church Recruitment Pkt/Flyers

1. Study Team Members have been updated to include new RAs and remove staff off the project.
2. Updated church fliers and welcome packet to include HUM# and reformatted for improved aesthetic.
3. Fully executed Collaborating Institution and Project Participation Agreements added to each church in 3-1.1* Performance Sites.
4. Removed churches from section 3-1.1 Performance Sites that are no longer participating in the study.

Amendment #3: Ame00128520 RCT

1. Changed statistical design from Stepped Wedge to RCT
2. Changed eligibility criteria to include updated booster guidelines per CDC
3. Expanded recruitment to include non-church community members to allow for public recruitment events, rather than faith-based recruitment events
4. Recruiting Vaccine Champions who will go through virtual training only. Newly recruited Vaccine Champions will not receive incentives and will not interact directly with participants.
5. Updated consent to include eligibility and recruitment changes noted above.

6. Updated enrollment numbers
7. Included of MMS messages
8. Update study team members.

Amendment #4: Ame00133699 Audit Edits

1. Add completed GCP trainings for all study team members.
2. Update Protocol
3. Update funding
4. Update consent
5. Update DSMB to DSC

Amendment # 5: Ame00136269 SPAN-flyer

1. Add Spanish translation of approved English recruitment flyer.
2. Edit team members.

Amendment #6: Ame00137511 New Ads, Staff

1. Add new social media ads
2. Edit team members

Amendment-7: Ame00138260 Data Direct, Staff

1. Recruitment Expansion to add Data Direct added to Protocol and application. Added recruitment Scripts in English and Spanish to 08-1.
2. Edit team members

Amendment-8: Ame00141536 Omicron Booster

1. Survey and content will be updated to reflectthe FDA updated guidelines for defining "up-to-date" as receiving the bivalent (“Omicron”) booster.
2. Staff members added/removed.
3. Enrollment target is increased to 800 to have power for analysis after guide changes.

Amendment-9: Ame00144824 Update Articulate, Enrollment

1. Increase Enrollment to 1000 to increase population eligible for analysis.
2. Update Vaccine Champion Articulate Training with up-to-date content related to Sept 2023 vaccine.
3. Update Public Articulate Training with up-to-date content related to Sept 2023 vaccine.

Amendment-10: Ame00146052 Protocol

1. Update protocol.

3.5 Appendices

APPENDIX 1: OUTCOME MEASURES

Variable	Time point(s)	Variable type	Outcome type
Demographics/patient characteristics (age, sex, gender, race, ethnicity, education, income)	t(0)	continuous, categorical	N/A
Participant SMS/MMS responses response for vaccine uptake		continuous, categorical	primary
Participant perceptions	t(1), t(2), t(3)	continuous	exploratory
Vaccine intention	t(1), t(2), t(3)	continuous	exploratory

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5 PROTOCOL SIGNATURE PAGE

Protocol Title: Community-Centered Interventions for Improving Vaccine Uptake for COVID-19: Getting to Yes, Michigan!

Protocol Number: Version 12.0

Protocol Version/ Date: February 26, 2024

Sponsor Name: National Institutes of Health

Declaration of Investigator

I confirm that I have read the above-mentioned protocol and its attachments. I agree to conduct the described trial in compliance with all stipulations of the protocol, regulations and ICH E6 Guideline for Good Clinical Practice (GCP).

Principal Investigator Name:
Ken Resnicow, Ph.D.

Principal Investigator Signature:

Date: 2/26/24