

Informed Consent Form

Community-Centered Interventions for Improved Vaccine Uptake for COVID-19 (CIVIC): Getting to Yes, Michigan! (G2YMI)

NCT05096260

Document Date: 2/24/2023

CONSENT FORM

DATE: 4/27/2026

**Getting to Yes: Increasing COVID-19 vaccination in Michigan
Community-Centered Interventions for Improved Vaccine Uptake
for COVID-19 (CIVIC)**

**Funded by: NIH Health and Human Services GRANT13282146
Award # 5R01MD016867-02**

National Clinical Trial (NCT) Identified #: NCT05096260

Principal Investigators: Erica Marsh, M.D. and Ken Resnicow, Ph.D.

Approved by IRB HUM00204174 DATA ANALYSIS



For questions about informed consent, please contact the IRB-HSBS at 734-936-0933 or irbhsbs@umich.edu.

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: "Getting to Yes": Increasing COVID-19 vaccination in Michigan" **Principal**

Investigators: Ken Resnicow, Ph.D., University of Michigan and Erica Marsh, M.D., MSCI, FACOG Michigan Medicine

Co-Investigator(s): Larry An, M.D, Michigan Medicine, Charles Williams, II, M.S.W., University of Michigan

You are invited to take part in a research study. This form contains information that will help you decide whether or not to join the study.

1.1 KEY INFORMATION ABOUT THIS STUDY

Things you should know:

- The purpose of the study is to increase understanding of the barriers and drivers of vaccine uptake and hesitancy; as well as increase vaccine uptake and decrease vaccine hesitancy through the implementation and evaluation of a multi-level intervention to increase vaccine uptake and decrease vaccine hesitancy through the implementation and evaluation of an individual level tailored messages.
- If you choose to participate, you will be asked to receive and respond to SMS/MMS messages, complete surveys regarding your views on the COVID-19 disease, vaccines, and its impact on your life.
- Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

Risks and Benefits to Participation:

- **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 individuals about their barriers and beliefs about the COVID-19 vaccine.
- **Risk Seriousness:** You may skip any questions that you feel are 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 participant 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; 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.
 - Electronic study data will be stored in a database on a separate, highly-restricted, secured server. Only the primary investigators and other authorized research team members will have access to the de-identified data. These standards will help to ensure that violations of confidentiality will be minimal.

- 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 others might benefit from this study in the future.

Participants who wish to receive communication training about COVID-19 and the vaccinations will receive a link to a training video from the Articulate 360 website.

2. PURPOSE OF THIS STUDY

The purpose of the study is to increase understanding of the barriers and drivers of vaccine uptake and hesitancy.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

- If you are 18 years old or older;
- AND have access to a phone that can receive and respond to SMS/MMS (depending on your phone carrier and mobile plan, data charges may apply);
- AND live in Michigan; AND at least one of the following two:
 - you have not received the COVID-19 vaccine including boosters AND can speak and read in English or Spanish;

3.2 OR you have received all doses, including boosters of the COVID-19 vaccine and wish to participate in the communication trainings AND can speak and read English.

- This study will recruit at least 400 participants.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

ALL participants agree to all of the following:

- participate over a 6-month period;
- receive SMS/MMS/text messages about the study, including links to web-based surveys;
- reply to at least 80% of these surveys, which can be completed on a phone, tablet, or computer;
- agree to read information about the COVID-19 vaccine on the website.

AND

IF UNVACCINATED/UNBOOSTED OR

- potentially be contacted by one of your community members to discuss your views.

IF VACCINATED WITH ALL DOSES

- to receive and practice communication training where you will learn skills for speaking to individuals about their barriers and beliefs about the COVID-19 vaccine.

4.2 How much of my time will be needed to take part in this study?

ALL participants can expect SMS/MMS messages weekly, for 6-months. These messages have either:

- links to surveys, or
- SMS/MMS requests to reply with short answers.

These should take under one-hour total to complete.

AND

IF UNVACCINATED/UNBOOSTED OR

- you may meet with a

IF FULLY VACCINATED

complete a 1-hour, self-paced, online

vaccine champion to discuss
your thoughts and values

communications training.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Because this study collects information about you, the primary risk of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

Breach of confidentiality (i.e. informational risks) is a potential risk in all research that collects or maintains personally identifiable information and may be the only risk in some studies. Participant contact information may be accessed by trained community members who have completed human subjects training and communications training, to speak with you about your barriers or beliefs about the COVID-19 vaccinations.

The researchers will try to minimize these risks maintaining all study related information on password-protected, secured servers.

5.2 How could I benefit if I take part in this study? How could others benefit? You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record and reported to the funder. The researchers will keep the information collected about you for the research. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

ALL participants may receive a Visa gift card or Amazon gift card for your participation in the study, as long as you remained enrolled. You will not receive incentive payments if you choose to withdraw before the study ends.

The University of Michigan Human Subjects Incentives Payment (HSIP) office will collect and safely store your name, address, email, phone, social security number, and payment amount for tax-reporting purposes. Your data will be stored on secured servers at the University of Michigan.

- If you receive more than \$600 in payments in a calendar year, this information will be sent to the Internal Revenue Service (IRS). Tax Form-1099 will be sent to your home.
- If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.
- If you don't want to share your contact information with HSIP, you may waive your incentive.

Incentives available:

IF UNVACCINATED/UNBOOSTED

- \$10 for the baseline survey taken at the beginning of the study,
- \$10 for the follow-up survey taken at the end of the study

7.2 Who could profit or financially benefit from the study results?

There are no individuals or organizations that may financially benefit from the study results.

This study is investigator-initiated, funded by the National Institutes of Health. There is one known conflict of interest with one researcher conducting this study. Rev. Charles Williams is a co-founder and officer of the board of directors for the Institute on National Social Inequities and Gaps in Health and Health Treatment (DBA “INSIGHT”), a student at the University of Michigan, and an investigator on the study. INSIGHT is a collaborator on this study and de-identified data may be shared with INSIGHT.

Research can lead to new discoveries (e.g., tests, apps, software, devices). Researchers, their organizations, such as U-M, research sponsors, and other entities, including companies, may potentially benefit from the use of the discoveries or data. You will not have rights to these discoveries or any proceeds from them.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? Personal information and survey responses will be stored on secured servers at the University of Michigan.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. This includes placement of your research information into the G2YMI study portal, sharing that may be used by vaccinated, enrolled, members of your community enrolled in the intervention. G2YMI de-identified data may be shared with other researchers who are studying COVID-19 vaccination.

Please note that a CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates can be found at the NIH CoC webpage:
<https://humansubjects.nih.gov/coc/index>

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the

Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

- Champions may have access to the information you provide to facilitate the study.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the research for study record-keeping. Your name and other information that can directly identify you will be stored in agreement with the regulatory rules that affect this research study. The researchers may contact you again as part of this project, or for future research.

All direct identifiers will be deidentified and stored on secured servers at the University of Michigan with limited password protected access. Those with access to all study data have completed human subjects training and are listed on the approved IRB application.

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. We will not keep your name or other information that can identify you directly after the completion of the study. If we share your information from G2YMI with other researchers it will be deidentified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different.

We would like to share your identifiable information with other researchers for future research. We will ask for your consent to do so at the end of this form. You can be a part of G2YMI without agreeing to this future use of your identifiable information.

8.4.1 Special Requirements

A description and summary of results of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished please email GettingToYesMI@med.umich.edu and note the study team is required to provide a reason for the withdraw.
- Express a concern about the study

Principal Investigator:

Ken Resnicow, Ph.D.

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Phone: 734-904-3888

Project Director:

Arthi Ramakrishnan, MS, CCRP

Email: arthrama@med.umich.edu

Phone: 734-615-8068

Project Manager

Emerson Delacroix, LLP, MACP

Email: emmed@med.umich.edu

Phone: 734-764-2014

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

11. OPTIONAL CONSENT

Consent to use and/or share your identifiable information for future research

The researchers would like to use your identifiable information for future research that may be similar to or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future research if you decline. We may also share your identifiable information with community members. You can contact us at any time to ask us to stop using your information. However, we will not be able to take back your information from research projects that have already used it.

_____ Yes, I agree to let the researcher(s) use or share my personally identifiable information for future research.

_____ No, I do not agree to let the researcher(s) use or share my personally identifiable information for future research.

Consent to be Contacted for Participation in Future Research

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

_____ Yes, I agree for the researchers to contact me for future research projects.

_____ No, I do not agree for the researchers to contact me for future research projects.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____