Informed Consent Form

TITLE: Promoting Engagement and COVID-19 Testing for Health (PEACH2)

NCT NUMBER: NCT06141850

IRB APPROVAL DATE: March 26, 2024

Emory University
Oral Consent Script
For a Research Study

Title: Promoting Engagement and COVID-19 Testing for Health (PEACH2)
IRB #: STUDY00006531
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Introduction and Study Overview

Thank you for your interest in the Project PEACH2 study on COVID-19 home testing and text message reminders for people affected by diabetes. We would like to tell you everything you need to think about before you decide whether or not to join the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. There are no consequences to you if you decide not to participate.

The purpose of the study is to understand how health messages delivered by text affect COVID-19 prevention and other health behaviors among people who are affected by diabetes. We also want to know what kinds of text messages about COVID-19 testing and prevention people affected by diabetes (with diabetes, at risk for diabetes, or caring for someone with diabetes) find helpful. To do this, we are asking people in Georgia who are affected by diabetes to agree to receive weekly text messages, complete three (3) surveys online, respond to a monthly text question about COVID-19 testing, and answer a few short questions about the text messages via text up to six (6) times. Some but not all participants will also be invited to participate in one (1) individual interview or to share their social media data with the team. Some may also be invited to participate in a second follow-up individual interview. All participants will receive text messages with information about COVID-19 and diabetes they might find useful.

If you join the study, you will be asked to participate in a trial that will last 12 months. You will be randomly assigned to one of two groups. Both groups will receive text messages on COVID-19 prevention; one of the groups will also receive messages about diabetes prevention and/or care. You will be asked to complete a survey at the beginning of the study, at the end of the 4-month trial, and again at 12 months. Each survey will take about 15-30 minutes to complete and will be completed over the internet. In the survey, we will ask you some basic questions about yourself such as your name, age, address, contact information, race, ethnicity, gender, health insurance status, disability, job, and household information. We will ask you about health behaviors including COVID-19 testing and COVID-19 vaccines. If you have diabetes or help take care of someone with diabetes, we will also ask you about your experience with diabetes care.

The study is funded by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health.

If you are willing, you may also be asked to agree to participate in a sixty-minute, individual interview about your experience with the text messages and your health behaviors while you were in the study. This will happen at the end of the 4-month period and not everyone will be asked to participate in an interview. Participants invited to participate in the interviews will be contacted by email or phone during the study period. Interested participants will be provided with more information about the interviews and will provide informed consent to be interviewed. There may also be an opportunity to participate in a second follow-up interview at the 12-month time point. Taking part in the interviews is optional and not required to participate in the study.

If you are willing, you can contribute additionally to the study by sharing your social media data with the study team. Participants invited to participate in the social media data collection will be contacted by email or phone during the study period. Interested participants will be provided with more information about how to provide social media data and will provide informed consent to provide this additional data. Taking part in the social media study is optional and not required to participate in the study.

The risks in this study are small. The survey questions or interview may make you frustrated, embarrassed, uncomfortable, tired, or bored. You may also experience mood changes when you think and talk about your experiences. Some other risks include loss of privacy and breach of confidentiality. Your name and information (including any medical information you provide us) will be kept confidential during the conduct of this research. Your study information will be stored in a secure computer server managed by Emory University. The Georgia Institute of Technology will send the text messages through a secure system. There is a very small chance of your name and information being accidentally released or breached. To avoid this happening, we will only use your randomly assigned study ID in the study records. We will give you emergency care if you are injured by this research.

This study is not designed to benefit you directly, but we hope it will benefit people affected by diabetes. By learning about what people think about COVID-19 testing, we hope we can help improve the outcomes for people at greater risk of getting COVID-19. Study participants will receive e-gift cards for their time and participation. Survey participants will receive a $25 e-gift card for completing the baseline survey, a $35 e-gift card for the 4-month survey, and a $40 e-gift card upon completion of the 12-month survey. Those that participate in an interview will receive a $25 e-gift card for each interview (up to 2). Participants contributing their data to the social media component will receive a $40 e-gift card. eGift cards will be emailed to participants when they complete each survey, interview or social media upload.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory University and Grady Health System employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance, the Grady Health System Office of Research Administration]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

People Who will Use/Disclose Your Information:

The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- National Institute of Diabetes and Digestive and Kidney Diseases is the Sponsor of the study. The NIDDK may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The NIDDK may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study, including the Grady Health System Office of Research Administration.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Research monitors and reviewer.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

If you agree, we will share some of your information with The Duke Clinical Research Institute (DCRI). Sharing your data with the DCRI is optional. The DCRI have signed a data transfer agreement, which is an agreement signed to help protect the privacy of your information. The DCRI is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies across the nation. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program designed to learn more about COVID-19 disease. If you join RADx-UP (this study), we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

The DCRI has two RADx-UP databases (systems that hold electronic information).
The first database only holds information that can identify you (called identifiable information). Examples are your name, address, email, and gender.

- These data will be stored at the DCRI. The DCRI will not share these data with the NIH.
- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- Only if you agree, by checking the #4 box below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.

The second database will not hold information to identify you. It will hold non-identifiable information.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

Contact Information

If you have questions about this study, your part in it, or if you have questions, or concerns about the research you may contact the following:

Dr. Mary Beth Weber, Principal Investigator
[redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at [redacted].

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at [redacted].

e-Consent
By checking "yes" in the boxes at the end of this form and entering the requested information, you consent to take part in those parts of the study. If you have any questions about anything in this document, please contact the study team by sending an email to [redacted] or calling [redacted]. You may also contact Dr. Mary Beth Weber or the Emory IRB Review Board at the contact numbers in the informed consent form.

First and last name _____

Email address _____

Mobile phone number _____

1) Do you agree to take part in the study? ☐Yes ☐No
2) Are you willing to be contacted about other studies that might be of interest to you? ☐Yes ☐No
3) Are you willing to be contacted to participate in an interview about this study? ☐Yes ☐No
4) Are you willing to be contacted about sharing your social media data with the study team? ☐Yes ☐No
5) Do you agree to let the Duke Clinical Research Institute (DCRI) collect information that can identify you, such as your name, address, contact information? ☐Yes ☐No
6) Do you agree to let the DCRI collect only your zip code and no other identifiable information? ☐Yes ☐No