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**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**
**UNIVERSITY OF CALIFORNIA, DAVIS**
**UNIVERSITY OF CALIFORNIA, MERCED**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

# Study Title: Healthy Family Project - Getting INFORMED to Stay Healthy
**(Study Participant Version)**

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| Research Project Director: | Janice Tsoh, Ph.D., Professor of Psychiatry.<br>UCSF, 401 Parnassus Ave, Rm 392 San Francisco, CA.<br>Phone: 415-502-8438; e-mail: Janice.Tsoh@ucsf.edu |

The "INFORMED" Project is a research study targeting Asian Americans with the goal of providing up-to-date information about COVID-19. "INFORMED," also stands for "Individual and Family Oriented Responsive Messaging Education." The researchers Drs. Janice Tsoh (UC San Francisco), Nancy Burke (UC Merced), and Susan Stewart (UC Davis) from the University of California, Joyce Cheng from the Chinese Community Health Resource Center (CCHRC), Dao Lor from The Fresno Center, Mai Pham from the Immigrant Resettlement and Cultural Center (IRCC), or their research staff will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are either Chinese, Vietnamese, or Hmong American and are 18 years of age or older.

## Why is this study being done?
The purpose of INFORMED is to understand and address barriers related to COVID-19 testing and vaccination. We want to know if the use of text or instant messaging with or without a lay health worker education will help Chinese, Vietnamese, and Hmong Americans to increase knowledge about COVID-19 testing and vaccination, and make well-informed decision about getting tested for COVID-19.

This study is funded by the National Institutes of Health (NIH). The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone.

## How many people will take part in this study?
About 255 people will take part in this study. About 15 people will participate as lay health workers, and 240 people will participate as study participants of the educational programs.

## What will happen if I take part in this research study?

If you choose to participate, this is what will happen next:

- You will first be asked to complete an initial survey. This survey may last for about 20 minutes. You may complete this survey online or by telephone with a research staff. This survey will ask about your background information, health and lifestyle health behaviors such as tobacco use or smoke exposure, and your views and experiences related to COVID-19 testing and vaccination.
- You will be randomly assigned by the researchers to participate in either one of these educational programs:
  - **Program A** – **12-week Automated SMS Text Messaging:** If you are assigned to this program, you will receive a weekly SMS Text message on a topic related to COVID-19 testing over 12 weeks. In addition, participants will receive as-needed messages on updates of COVID-19 testing related information. The messages will be responsive to the rapid evolving developments and changes related to COVID-19 testing guidelines. Some of the messages will include a link to allow participants to get to the entire message/information on the study website.
  - **Program B** – **12-week Automated SMS Text Messaging Plus Lay Health Worker Educational Outreach**:
    a) If you are assigned to this program you will receive a weekly SMS Text or instant message on a topic related to COVID-19 testing as described in Program A above.
    b) In addition to receiving text messages, you will receive a Lay Health Worker (LHW) Educational Outreach Program, which includes 2 group sessions and 2 individual follow-up contacts:
       i. 2 group educational sessions:
          - A LHW will invite you to participate in up to 2 small group educational sessions via video calls like Zoom or another video conferencing platform (such as WeChat Video Chat) that are mutually agreed upon by both the LHW and you.
          - Each educational session will be approximately 1 hour long, during which LHW will present COVID-19 testing related information.
          - You may participate in these educational sessions with other INFORMED participants.
          - Sessions 1 and 2 may be scheduled approximately 2-3 weeks apart.
          - At some of the small group sessions, a research staff may stay for the entire session to make observations and/or to make a digital recording of the small group sessions to provide video and audio of the sessions for research analyses. No observation and/or digital recording will be made if you or anyone participating in the session does not provide permission for one or both activities. The digital recording will be accessible by study staff only and will be destroyed after study analyses have been completed.
       ii. 2 individual follow-up contacts:
          - You will receive two follow-up contacts from your LHW, which can be in the forms of a telephone call, text or instant messages, or other formats that both you and your LHW have agreed to use.
          - Each contact will occur within 1-2 weeks after each group session.

- Regardless of which educational program you are assigned to, you will be asked to complete brief surveys throughout the study. These surveys will be conducted by our research staff over the phone or can be completed online. You will be asked at Weeks 4, 8, 12 and 16 to complete a short survey by phone or online. These surveys will ask you about your health, lifestyle health behaviors, and your views and experiences related to COVID-19 testing and vaccination.

## How long will I be in the study?

Participation in the study will include:

- 1 initial survey (about 20 minutes),
- 3 surveys throughout the duration of the intervention (Weeks 4, 8, and 12) to be completed over the phone or online (about 10 minutes each, total of 30 minutes)
- 1 final survey (Week 16) to be completed over the phone or online (approximately 20 minutes)
- 12 weekly text messages (reading time approximately 1 minute, total of 12 minutes)
- If you are assigned to Program B (12-week Automated SMS Text Messaging Plus Lay Health Worker Educational Outreach), you will be asked to participate in:
    - a total of 2 meetings over Zoom or other video conferencing platform (1 hour each, total of 2 hours), and
    - 2 individual follow-up contacts (calls or instant messaging) with your lay health worker (10 minutes each, total of 20 minutes).

We estimate the total time of participation will be less than 4 hours over 4 months.

These activities will take place over 4 months and 15 minutes.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the researcher or the staff person right away if you wish to stop being in the study. The researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest or if you do not follow the study rules.

## What side effects or risks can I expect from being in the study?

- Some of the questions from the surveys or discussions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.

- Having a researcher present at the meetings to conduct observations, and having voice and face recorded at any of these meetings may likely make you feel uncomfortable. However, you may let the researcher know that you do not wish to have the researcher present, and/or have your voice or face recorded. Without permission from you and everyone present in the group meeting, no observations, audio or video recordings will be made.

- Another risk of participation is the potential for conflict between a family member participant in the study when the two people have a disagreement on beliefs or actions to be taken for COVID-19 testing as discussed in the meetings. Examples can include when

one member of the family wants to be tested for COVID-19, but the other does not feel comfortable getting tested.

## Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. The results of this study may help health professionals better understand and learn more about Chinese, Vietnamese, and Hmong Americans and how they think about COVID-19 testing and vaccinations.

## What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, nothing will change. You will not lose any of your regular benefits, and you can still get the same care and services.

## How will my information be used?

Researchers will use the information that you provide to conduct the study. Once the study is done using your information, we may share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. Because the data cannot be linked back to you, we will not ask you for additional permission to share this de-identified information.

This study is also part of the RADx-UP program funded by the National Institutes on Health. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. The RADx-UP is a national health research program to learn more about COVID-19 disease. The information you provide through your participation in this study, will be combined with the information provided by other participants who join the NIH RADx-UP program. Therefore, the information you provide will also help researchers to understand how to help more people at risk for or with COVID-19.

## Will information about me be kept private?

We will do our best to make sure that the personal information discussed in the surveys and small group sessions is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

As required by the National Institutes of Health, the results of this study will be posted on ClinicalTrials.gov, and public website that allow public access to information about clinical studies on a wide range of health conditions. Results will be presented in an aggregated format, thus no individual information will be included in these reports. Similarly, if information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of the Chinese Community Health Resource Center
- Representatives of The Fresno Center

- Representatives of the Immigrant Resettlement and Cultural Center

Because the outreach groups, telephone calls, or instant messaging with your lay health worker include discussions of personal opinions, we will do our best to protect each participant's privacy. Your lay health worker will also ask you and other participants in the group meetings not to tell anyone outside the group what any particular person said in the group, which means all participants should verbally agree to keep everything discussed during the meetings confidential. Your lay health worker has been trained and has agreed to avoid discussing the information you provide with other individuals without your permission. However, the researchers cannot guarantee that everyone will keep the discussions private. After the study is completed, the audio and video recording will be destroyed. If you do not want to have any recordings taken at the meeting, please let us know.

## What are the costs of taking part in this study?

There is no financial cost for being in this study.

## Will I be paid for taking part in this study?

In return for your time and effort, you will be paid $100 in gift cards or cash for taking part in this study for completing all 5 surveys. You will receive $20 for completing each survey, which includes the initial survey, surveys at weeks 4, 8 & 12, and the final survey at Week 16.

## What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care the way you usually do.

## Who can answer my questions about the study?

You may ask the research staff. You can talk to the researcher(s) about any questions or concerns you have about this study. Contact the INFORMED project staff at (415) 677-2473 or appropriate researchers from the table below:

| Name | Institution | Role | Phone Number | E-mail |
|---|---|---|---|---|
| Janice Tsoh | UCSF | Principal Investigator | (415) 502-8438 | janice.tsoh@ucsf.edu |
| Joyce Cheng | CCHRC | Co-Investigator | (415) 677-2473 | joycec@chasf.org |
| Nancy Burke | UC Merced | Co-Investigator | (209) 455-0160 | nburke2@ucmerced.edu |
| Susan Stewart | UC Davis | Co-Investigator | (916) 734-7217 | slstewart@ucdavis.edu |
| Dao Lor | The Fresno Center | Site Coordinator | (559) 892-9841 | dao.lor@fresnocenter.org |
| Mai Pham | IRCC | Site Coordinator | (408) 828-9254 | maiphn@yahoo.com |

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact the please call the Institutional Review Board at (415) 476-1814.

## CONSENT

You will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, please press the "CONTINUE" button to start the initial survey.