# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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| Study Title | **"Motivate Vaccinate Activate":** *An effectiveness-implementation trial to assess the impact of a multi-component community-based intervention to increase RSV vaccine uptake among Latino older adults* |
| Principal Investigator (Person in charge of this study)<br><br>Site Principal Investigator, MLVS | *Carina Marquez, MD, MPH*<br>*Associate Professor of Medicine*<br>*UCSF Department of Medicine*<br>*415-476-4082, carina.marquez@ucsf.edu*<br><br>*Efrain Barrera*<br>*Interim Executive Director, MLVS*<br>*415-794-6699, efrain@mlvs.org* |
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## 1. Why have I been given this document?

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

## 2. Do I need to take part in this research study?

No. Taking part in research is voluntary. If you don't want to take part there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to

you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

## 3. This section describes key information to consider about this study

### 3.1 Why is this study being done?

This study is being done to compare different ways of increasing awareness and use of the Respiratory Syncytial Virus (RSV) vaccine to see what's most effective.

### 3.2 How long would I be in this study? How many study visits are there?

The main part of the study will last 2-3 months with up to 4 visits done in person or by phone or virtual meeting platform such as Zoom. We may also ask you to take part in an interview about the study and the RSV vaccine up to 2 years after starting the study.

### 3.3 What are the procedures with the most risk in this study?

Answering sensitive questions about your health or preferences for vaccination can cause stress, anxiety or discomfort.

### 3.4 What risks and discomforts are most severe? What risks and discomforts are most common?

The risk that has the most potential to be severe is loss of privacy in the unlikely event your information is disclosed to people outside the study. The most common risk you may experience is mild discomfort when answering certain questions about your health.

We will tell you more about risks and discomforts later in this form.

### 3.5 Are there benefits to taking part in this study?

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

### 3.6 What are my other options if I don't want to take part in this study?

You may be able to take part in another study if one is available.

## 4. How many people will take part in this study?

About 400 people will take part in this study at UCSF and Mission Language Vocational School (MLVS) in San Francisco.

## 5. Who is paying for this study?

This study is being paid for by the National Institutes of Health.

## 6. Do any UCSF or MLVS researchers of this study have financial interests that I should know about?

No.

## 7. What are the research procedures of this study?

After signing this consent form:

- We will first administer a questionnaire with questions about your background, your knowledge of RSV and the RSV vaccine, and other topics. The questionnaire will take about 30 minutes to complete.
- We will randomly assign you to one of two groups. How your group is chosen is like flipping a coin or rolling dice. You have a 50% chance of being placed in either group.

If you are assigned to Group 1:

- You will receive information about the RSV vaccine and how to schedule an appointment to receive the vaccine.
- 4 weeks after you start the study, you will receive a text message about the RSV vaccine with more information and ways to schedule

an appointment. The message will be sent using a company called Twilio, which will collect your phone number to provide this service.
- About 2 months after you start the study, staff will administer a questionnaire asking questions about RSV and the RSV vaccine, whether you received the vaccine and the location you received it, and other questions. The questionnaire will take about 30 minutes to complete. Staff may also review your medical record or the California Immunization Registry (CAIR) for information on your RSV vaccine status.

If you are assigned to Group 2:

- You will take part in the same activities as described above for Group 1.
- In addition, up to 2 weeks after you start the study, a community health worker will provide a 20-30 minute counseling session on RSV. The counseling will include information about RSV infection and vaccines. The counselor will also offer assistance in finding a location and making an appointment for receiving the vaccine if you are interested.

A small number of participants (10-20 per group) will also be offered to take part in an interview on vaccines, including the RSV vaccine and human papilloma virus (HPV) vaccine, on what impacts decisions about whether to get the vaccines, and your opinion about the study. If you take part, we will record the audio from this interview and recordings will be transcribed. Once the recordings are transcribed, we will delete the audio. The transcripts will be handled as confidentially as possible, and all records will be coded so that no person outside the study group can identify you personally and any personally identifying information will be removed.

## 7.1 Where do the procedures happen?

Study procedures will be by phone, through a web-based meeting platform or will be done in-person at the UCSF Clinical Research Center at Zuckerberg San Francisco General Hospital, at the Mission Language Vocational School (MLVS) or other community locations affiliated with the Latino Task Force.

## 8. What are the risks of this study?

Risks related to this study include:

- Loss of privacy in the unlikely event your information is disclosed to people outside the study.
- Answering sensitive questions about your health or preferences for vaccination can cause stress or anxiety. You may refuse to answer any question or stop at any time.

**Randomization risks**: You might be put into a group that receives something that is not as effective as another group.

## 9. Will I be paid if I take part in this study?

In return for your time and effort, you will be paid up to $80-$210 for taking part in this study. You will be paid $40 after completing the first study questionnaire at enrollment and $40 after completing the questionnaire 2 months after starting the study. If you are randomly assigned to the group that also receives counseling on RSV, you will be paid an additional $30 if you attend the counseling session.

If you are asked to take part in an in-depth interview, you will be paid an additional $100 for completion of the 90-minute interview.

A company called Greenphire is working on behalf of the study to pay participants through a reloadable debit card. If you receive payments in this way, Greenphire will need to collect your name and email address to set up your payment account.

## 10. Will I be reimbursed for expenses if I take part in this study?

You will not be reimbursed for expenses if you take part in this study.

## 11. How will my information be used?

Researchers will use your information to do this study. Once the study is done, we may use your information for other research studies in the future. We will share it with other researchers to be used in their studies. We will

not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

Your research data will be stored in a computer database. Other researchers and companies can use the database to do their own research. There are different types of databases. Some are available to the public. This is called “unrestricted access.” Others require special permission to use. This is called “restricted access

## 12. How will information about me be kept confidential?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But we cannot guarantee total privacy. Some information from your medical records may be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. People involved with your future care and insurance may become aware that you participated in this study. They may see information added to your medical record. Study tests and information obtained from you will be part of your research records. This information may be added to your medical record. Your personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your name and other personal information will not be used.

## 12.1 Who may review my research information?

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 University of California
- Representatives of the National Institutes of Health
- Representatives of the Office of Human Research Protections (OHRP)
- Representatives of the Mission Language Vocational School

## 12.2 Certificate of Confidentiality

This study has something called a Certificate of Confidentiality. This helps keep your information private. Researchers can't be forced to share your information with others like courts or law enforcement.

There are some things that the certificate does not stop:

- Reporting abuse of children or elders, or if you or someone else is in danger.
- Reporting of certain diseases.
- Groups (like those listed in 12.1) from checking the research records to make sure the study is going okay.
- Agencies from getting information if they need it for safety reasons.
- Your information from being used in other research if it follows the rules.

The certificate doesn't stop you from:

- Talking about being in this research study.
- Looking at your own medical records.

## 13. Does this study involve testing of diseases and conditions that must be reported to the public health department?

No, this study does not involve testing for reportable diseases and conditions.

## 14. What happens if I am injured or feel harmed because I took part in this study?

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

## 15. Are there any costs to me for taking part in this study?

No. There is no cost to you or your insurer if you take part in this study. However, you may need to pay for items such as parking and transportation.

You or your insurer will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

## 16. Can I stop being in the study if I want to?

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you.

If you stop being in the study, any data we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

## 17. Can I be removed from the study by the Principal Investigator?

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

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

You may choose to take part or not to take part in this study. It's your choice. 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. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

## 19. Who can answer my questions about this study?

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

### 19.1. Where can I get more information about this study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

## 20. Consent

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

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say "No" to this study now or at any point without penalty.

If you wish to take part in this study, please sign below. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

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|---|---|
| Date | Participant's Signature for Consent |
| Date | Person Obtaining Consent |
| Date | Witness Signature – if applicable |