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Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

 

# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

**UNIVERSITY OF CALIFORNIA, LOS ANGELES**

**STUDY INFORMATION SHEET**

**Study Title:** Multimorbidity and Medications: The Unheard Perspective of Older Adults

Dr Janice B. Schwartz from the Department of Medicine at the University of California, San Francisco and Derjung Mimi Tarn, MD, PhD from the Department of Family Medicine at University of California, Los Angeles, are conducting a research study. This study is being conducted on behalf of the U.S. Food and Drug Administration (FDA).

# Why is this study being done?

# Older people with multiple medical problems or taking multiple medicines are not usually enrolled in research studies of new medical therapies but may receive prescriptions for them after they are in use clinically. The researchers are trying to learn what older people with multiple medical problems or taking multiple medicines think about research studies of new medical therapies. About 1,000 people will participate in this study.

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

If you agree to be in this study and are eligible, you will complete a one-time survey either on the internet, on paper or by phone. The survey asks about you, and your thoughts and opinions about research studies. It will take you about 15 minutes to complete the survey.

# How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, the survey information may be shared with other researchers for use in studies in the future. Your name or any other personal information that would let the researchers know who you are will not be shared. No additional permission to share this de-identified information will be asked.

# Are there any risks to me or my privacy?

The researchers will do their best to protect the information collected from you. Information that identifies you will be kept secure to the extent permitted by law. The completed surveys will be kept secure to the extent permitted by law and separate from information that identifies you. Only a small number of researchers will have direct access to completed surveys. If this study is published or presented at scientific meetings, names and other information that might identify you 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 University of California
* Representatives of the Food and Drug Administration (FDA)
* Representatives of the Office of Human Research Protections (OHRP)

# Are there benefits?

There is no benefit to you. The survey results will be used for research.

# Can I say “No”?

Yes, you do not have to complete a survey. If you choose not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from UCSF or UCLA.

# Are there any payments or costs?

In appreciation of your participation in this study, you will receive a $25 electronic or physical gift card in approximately 6-8 weeks after you complete the survey. There are no costs to you.

# Who can answer my questions about the study?

You can talk with the research team about any questions, concerns, or complaints you have about this study. Contact the study team:

UCSF participants: Alveena Thomas at alveena.thomas@ucsf.edu or (925) 200-1149

 UCLA participants: Ariga Eyvazi at AEyvazi@mednet.ucla.edu or (310) 794-8242

If you wish to contact the Investigators, you may reach Dr. Schwartz at Janice.Schwartz@ucsf.edu or (415) 519-3161 or Dr. Tarn at DTarn@mednet.ucla.edu

or (310) 794-8242.

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 call the office of the Institutional Review Board at 415-476-1814.