

U.S. Food and Drug Administration  
Generic Clearance: Request for Data to Support Social and Behavioral Research  
OMB Control Number 0910-0847  
Gen IC Request for Approval

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

**1. Statement of Need:**

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

The older adult population consumes the majority of prescription medications marketed in the United States yet is under-represented in drug development studies, clinical testing, and formal post-marketing evaluations. The high rate of adverse drug effects, discontinuation, and poor adherence to prescribed medications are likely related to unrecognized considerations for older adults and the challenges they face. Older adults commonly have multiple chronic conditions, take multiple medications, but also have functional and cognitive limitations that are not characterized in electronic health care records. These “typical” older adults have had limited inclusion in drug development and evaluation trials. This may lead to insufficient data on the efficacy and safety among the ultimate users of medications.

The purpose of this research is to increase FDA’s understanding of beliefs, attitudes, barriers and enablers of participation in clinical trials among older adults living with multiple chronic medical conditions and taking multiple medications. This will help design and develop effective recruitment strategies directed towards this patient population, which in turn is essential for enhancing the safety and efficacy of new drugs.

The research aligns with the FDA’s objectives to “strengthen social and behavioral science to promote informed decision-making about FDA-regulated products.” It meets the agency’s goals by identifying and filling gaps in key areas of knowledge; reaching diverse audiences; assessing perceptions and attitudes about clinical trial participation; and identifying strategies to improve clinical trial participation in older adults. This study will be used to support educational and public information programs (21 U.S.C. Section 393(d)(2)(D)).”

**2. Intended Use of the Information:**

Information collected will inform the design of future clinical trials, minimize the observed obstacles and maximize or add the motivators identified in order to achieve enrollment in clinical trials that better represent the ultimate treatment populations to assure that efficacy and safety are addressed during the evaluation of new medical therapies. This quantitative survey portion of the study complements the qualitative portion of Generic IC OMB Control Number 0910-0497 entitled “MUltimorbidity and Medications: the unheard perspective of older Under-Represented Racial and Ethnic Minority Adults” approved on October 13, 2022 (ICR Reference Number 202008-0910-021). The survey questionnaire addresses different perspectives of clinical trials enrollment for older adults that complements the focus group moderator guide. The survey questionnaire is available in both English and Spanish to reach a diverse population that meet the

study eligibility and does not often partake in clinical trials. The qualitative focus groups are conducted in older Asian population of Chinese origin on their perspectives of factors that inform their decision making about whether to join clinical trials in which they take a medicine while the quantitative survey questionnaires are administered to older diverse population with multiple medical problems or taking multiple medications and are not usually enrolled in clinical trials. The focus group discussions elicit additional knowledge and themes that may be unique to one group and are only conducted in Asian population of Chinese origin due budget constraint and manpower of study staff; future studies plan to expand to other underrepresented populations to capture an in-depth understanding of their voices via the qualitative method. Combining the two types of data means maximizing benefits from both the detailed, contextualized insights of qualitative data and the generalizable, externally valid insights of quantitative data. The strengths of one type of data often mitigate the weaknesses of the other. Mixed method approaches allow researchers to use a diversity of methods, combining inductive and deductive thinking, and offsetting limitations of exclusively quantitative and qualitative research through a complementary approach that maximizes strengths of each data type and facilitates a more comprehensive understanding of health issues and potential resolutions.

The data collected will not be used for the purposes of making policy or regulatory decisions. Rather, the data will provide a comprehensive perspective of older Americans on medical therapeutic but are under-represented in clinical trials that studied the efficacy and safety of those therapeutics. With a better understanding of their beliefs, attitudes, and knowledge of clinical trials participation, future recruitment strategies and education materials can be designed to address the gaps.

### **3. Description of Respondents:**

Study participants will include adults aged 65-years-old and above living in the community who have experience with drug products.

### **4. How the Information is Collected:**

Information will be collected with surveys that will be available on-line or via postal mail or telephone for those requesting assistance. The survey has been created in English and translated into Spanish as a significant portion of older patients receiving multiple medications are Hispanic/Latino and have Spanish as a primary language. The survey has been translated to Spanish by an American Translators Association certified entity. Surveys will be housed in a secure Qualtrics platform. This platform serves the purpose of wide reach to eligible individuals worldwide, can be used through a computer or a mobile device, and provides anonymity for participants. Surveys completed on paper (or by telephone) will have anonymized data entered in the Qualtrics database by research staff.

Invitations, sent via email and postal letter, for participation will contain the title, an explanation of the research being conducted, the expected length of participation, any incentive amount that may be provided for successful completion of the survey, and how an individual's data will be kept secure to the extent permitted by law.

### **5. Confidentiality of Respondents:**

a) The study information sheet provided during the recruitment phase states:

“We will do our best to protect the information we collect 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 as well 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.”

“Researchers will use your information to conduct this 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.”

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)

b) Our survey instrument also displays the following statement: “Your answers will be kept secure to the extent permitted by law.”

## **6. Amount and Justification for Proposed Incentive:**

An incentive is offered for this research. Participants will be provided a gift card of \$25 in appreciation for participation in the survey, an amount determined based on average hourly wages among residents of the California. According to the U.S. Bureau of Labor Statistics, the *average hourly wage* of *United States* citizens as of July, 2022 was \$32.27. Focus group participants are older adults. Older adults are a unique and hard-to-reach respondent group as usual communications and outreach efforts alone may not appropriately identify existing barriers to participation including high opportunity costs. Additional justification for providing the dollar amount in compensation is included below.

The token of appreciation in this study is intended to recognize and thank each participant for taking the time to answer the questions as honestly as possible. The cost of living in the Los Angeles Metropolitan area is estimated to be 41%-49% higher than the national average and costs in the San Francisco Bay Area are estimated to be twice the national average. The amount of the token of appreciation accounts for recruitment from this geographical area in light of the additional factors discussed below.

### **Older adults involvement in research**

Recruiting older persons with diverse health statuses as participants in research projects is a challenge for health researchers, particularly because persons with health impairments and in socially disadvantaged living conditions are difficult to reach. Persons in deprived living conditions and with ill health often face special barriers that may hinder them from participating in society in general, as well as in research. Including such groups is therefore a major methodological challenge for empirical research. Against this background, these individuals are ‘hard-to-reach’. Strategies to increase enrollment of older adults have been studied and four central steps have been identified with “offer incentives” as the second central step. The successful strategies of using incentives included small monetary incentives.

**7. Questions of a Sensitive Nature:**

The survey does not include questions of a sensitive nature.

**8. Description of Statistical Methods:**

Trained research staff of the University of California at San Francisco and at the University of California at Los Angeles will be responsible for distributing invitations for participation, data collection, data cleaning, and analysis of the data. Analysis will include descriptive analyses of the study participants and quantitative analyses with frequency and proportions of respondents selecting options in survey responses. Multi-variate analysis could potentially be performed when sample size and data distribution allows and will be guided by the initial results of the descriptive analyses. Statistical analyses will be performed using Statistical Analysis System (SAS) v.9.4 or R.

**9. Burden Hour Computation:**

Type/Category of Respondent	No. of Respondents	Participation Time (mins)	Burden (hours)
Survey screener respondents	1,150	5	95.8
Survey respondents (> 65 years of age)	1,000	20	333.3
Total	1,150	--	429.1

**10. Date(s) to be Conducted:**

The online survey will take place March – May 2023.

**11. Requested Approval Date:**

March 15, 2023

**12. FDA Contacts:**

Program Office Contact	FDA PRA Contact
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