United States Food and Drug Administration
Generic Clearance: Focus Groups as Used by the FDA
OMB Control Number 0910-0497
Gen IC Approval Request

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Co-creation of Digital Tools to Enhance Young Adult Minority Participation in COVID-19 Trials

1. Statement of Need:

Though diversity in clinical trials has become an important priority advanced by federal agencies including the FDA, the National Academies of Science has recently noted insufficient progress and documented the urgent need to redouble efforts to diversify clinical trials and research for underrepresented minorities (National Academies of Science, 2022). The purpose of this research is to increase the FDA's understanding of diverse minority and ethnic young adults' knowledge, attitudes, and experiences with clinical trials as a first step towards creating more culturally competent messages and educational materials to increase diversity in clinical trials. 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:

Focus group data collected on racial and ethnic minority young adults' knowledge, attitudes, and experiences with clinical trials will inform the development of digital educational tools to increase diverse young adults' participation in clinical trials. This study will be used to support educational and public information programs (21 U.S.C. Section 393(d)(2)(D))

3. Description of Respondents:

The study will include a series of focus groups with each participant attending two focus groups. Up to 176 individuals will be recruited to achieve a goal of 128 participants into 32 focus groups (approximately 8 per group).

Inclusion criteria:
(1) 18-29 years of age upon recruitment and data collection;
(2) live in the Los Angeles-Long Beach-Anaheim Metropolitan Statistical Area;
(3) proficient in English, i.e., read, write, and speak; and
(4) should not have any mental health issues as defined by DSM V.

Focus group stratification
Race: Asian, Black/African American, White
Ethnicity: Hispanic/Latino
Sex: male, female
Educational attainment: high school diploma or less, some college or more

4. How the Information is Collected:

Information will be collected with focus groups. A market research company will recruit eligible individuals via phone calls to individuals in an existing pool of potential research participants. Potential participants will be contacted, provided a description of the research being conducted, and screened for eligibility. Eligible individuals who agree to participate will be assigned to a focus group time and sent a URL to an informed consent form that provides detailed information about the research being conducted and an online survey to be completed prior to the online focus groups.

Focus groups will be conducted by trained research staff based at California State University, Fullerton (CSUF). Each session will include up to three members of the study team and up to 11 participants (with a target of 8 participants) per group. Interviews will be audio and video recorded and transcribed.

Given the ongoing COVID-19 public health emergency, all data will be collected from participants via web-based focus groups on Zoom. Conducting focus groups on Zoom also contributes to maximizing participant diversity.

5. Number of Focus Groups:

A goal of 8 participants, with up to 11 participants, will be included in each focus group. A target of 128 and up to 176 participants will be included in 32 online focus groups.

6. Amount and Justification for Proposed Incentive:

Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

If yes, describe the incentive and provide a justification for the amount. If no, delete this instruction.]

Participants will be a provided a gift card of $75 as a token of appreciation for participation in each focus group, an amount determined based on average hourly wages among residents of the Los Angeles-Long Beach-Anaheim Metropolitan Statistical Area. Focus group participants will be young adults from racial and ethnic minority groups, at least half of whom will be of low socioeconomic status (i.e., low educational attainment). These three qualities – young adult age, racial and ethnic minority status, and low socioeconomic status – make participants in this study 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.

- In order to make progress toward ameliorating the continued and pervasive absence of underrepresented and hard-hard-to-reach groups such as racial and ethnic minorities, those from low socioeconomic backgrounds, and young adults in public health research, incentives are often provided to increase participant engagement, particularly in the provision of data. Financial incentives are a valuable and regularly used strategy that promotes participation in research studies, especially when determination of payment is based on the cost and effort expended by the participant as a form of respect and just reward for willingness to participate (Bierer et al., 2021, Bonevski et

al., 2014). Use of financial incentives can enhance enrollment, without undue coercion of any particular population, and can serve as a means to equalize study participation.

- 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. The amount of the token of appreciation accounts for recruitment from this geographical area in light of the additional factors discussed below.

- **Racial and ethnic minority involvement in research**. This study's objective is to hear from underrepresented racial and ethnic minorities about participation in clinical trials. Racial and ethnic minorities have historically been underrepresented in clinical trials for clinical therapies as a whole and this continues to the present (Clark et al., 2019, National Academies of Science, 2022). Some barriers to participating in research studies for racial and ethnic minorities include, but are not limited to, mistrust in the research or research team, lack of comfort with the study protocols, time and resource constraints associated with participation, and lack of awareness about the existence and importance of clinical trials (Bonevski et al., 2014, Clark et al., 2019, National Academies of Science, 2022). To encourage a more representative and diverse sample to willingly engage in this project about drug development processes, it is advantageous to make their participation justifiable. This is especially important to this project as it is seeking to reach those who have systematically experienced greater obstacles to health based on characteristics historically linked to discrimination or exclusion (e.g., race or ethnicity, socioeconomic status) (Warren et al., 2021).

- **Socioeconomic status**. Participation in research studies can create barriers especially to economically disadvantaged populations due to the time commitment and opportunity costs required for participation in research. Participation in research can burden individuals from low socioeconomic backgrounds if there is no token of appreciation provided to reimburse them for their efforts and compensate them for their time. Incentives ensure the participant is not left financially worse due to their participation in the research study (Bierer et al., 2021). The Council for International Organizations of Medical Sciences (CIOMS) as well as FDA and the office of Human Research Protections support the position of providing a token of appreciation to research participants for expenses incurred due to their contribution to research studies (e.g., costs of child or elder care, transportation, and meals). This practice encourages the participation of lower socioeconomic status individuals, a target group for inclusion in this study, and provides just compensation for their time and effort (Bierer et al., 2021; Warren et al., 2021).

- **Young adult age**. Young adults participate in research studies at lower rates than other age populations (Keegan and Parsons, 2018, Tate et al., 2014). The transitional period of young adulthood which includes frequent changes in living, academic, and work status making it difficult to locate them for potential research studies (Hays et al., 2020). Changing contact information and losing interest over the duration of a study have been shown to result in low young adult participation in research studies (Sequiera et al., 2015) as do attitudinal characteristics such as lower levels of developmental and emotional maturity, cognition, and autonomy unique to young

adults (Barakat, et al., 2014). Appropriate incentives for young adult participation can help reduce these barriers to participation in research studies.

Provision of financial incentives is a key strategy to improve recruitment of hard-to-reach populations such as those to be recruited in this study (Bonevski et al., 2014) and should be done fairly and justly (Bierer et al., 2021). Taken together, cost of living adjustments and the hard-to-reach nature of the population of participants for the study project to an incentive amount of $75 per focus group, considered a fair and just amount that will adequately support the targeted enrollment goals of the study, thereby avoiding wasted resources, increased costs, barriers to timely completion of the study from poor participant recruitment (Bonisteel et al., 2021).

7. Questions of a Sensitive Nature:

None

8. Description of Statistical Methods:

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. The market research firm Assistance in Marketing will recruit participants and schedule focus groups. Invitations to participate in focus groups and screening will take place via phone calls to individuals on existing participant panels. Trained research team members from CSUF will moderate focus groups using a semi-structured focus group guide.

The information gathered will be qualitative in nature, focusing on participants barriers, beliefs, and attitudes related to clinical trials.

9. Burden:

Type/Category of Respondent	**No. of Respondents**	**Participation Time (minutes)**	**Burden (hours)**
Session 1 online focus group participation (>18 years of age)	176	60	176
Session 2 online focus group participation (>18 years of age)	176	60	176
Total	**352**	60	**352**

10. Date(s) to be Conducted and Locations:

Focus groups will take place August 2023 – Dec 2023 using an online modality. All participants will be residents of the Los Angeles-Long Beach-Anaheim Metropolitan Statistical Area.

11. Requested Approval Date: July 1, 2022

12. FDA Contacts:

Program Office Contact	FDA PRA Contact
Christine Lee ChristineS.Lee@fda.hhs.gov	JonnaLynn Capezzuto Jonnalynn.capezzuto@fda.hhs.gov

13. Certification: In submitting this request, I certify the following to be true:

a) The collections are voluntary;
b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
c) The collections are noncontroversial;
d) Personally identifiable information (PII) is collected only to the extent necessary[1] and is not retained; and
e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.[2]

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[1] For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.
[2] As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

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