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

Title of Gen IC: Focus Groups Examining Consumer Reporting of Adverse Events

1. Statement of Need

To protect the health of the public, it is important for the Food and Drug Administration (FDA) to promptly identify potential safety signals as early as possible. Voluntary reporting of adverse events related to human medical products, referred to here as adverse drug events (ADEs), by patients, consumers, and healthcare providers is a critical mechanism by which FDA identifies potential signals related to adverse events and quality problems with FDA-approved and compounded drug products. This information informs FDA's regulatory decision-making and actions, such as updating a product's labeling information, issuing compounding risk alerts, restricting the use of the drug, or removing a product from the market. It is critical that all racial and ethnic groups participate in voluntary ADE reporting so that FDA may identify safety signals with more precision and determine whether the ADEs disproportionately affect certain populations of patients. MedWatch is the FDA program for reporting ADEs and product quality problems associated with human medical products. FDA Adverse Events Reporting System (FAERS) is the database that contains the voluntary ADE reports submitted to FDA through MedWatch. Patients and consumers may report ADEs to FDA by submitting MedWatch Form 3500B.

These focus groups will explore the perceptions of, attitudes about, and access to adverse event reporting using MedWatch among racial and ethnic minority patients and consumers.

2. Intended Use of the Information

The proposed research is a companion study to a retrospective analysis of the MedWatch database for ADE reports by race/ethnicity and other demographic variables. The purpose of this focus group study is to provide insight to FDA about barriers to reporting adverse event data among minority populations. Information shared about these barriers may subsequently be used to identify strategies for outreach and engagement among these groups to increase the reporting of ADEs to MedWatch.

3. Description of Respondents

The research project will consist of a total of 12 online focus groups with adult (age 18 or older) participants who self-identify as Hispanic, or non-Hispanic Black, non-Hispanic Asian, non-Hispanic Native Hawai'ian/Pacific Islander, non-Hispanic American Indian/Alaska Native, or non-Hispanic White. Each online focus group will consist of no more than 6 participants. Approximately one third of study participants will be taking (or will have previously taken) one of the prescription drugs (e.g., allopurinol, diabetes medications, or anticoagulants (e.g., warfarin)) for which certain racial or ethnic minorities are at an increased risk for serious ADEs. All focus groups will be conducted in English. The groups will be segmented by race and ethnicity and participants' level of education (see Table 1). Gender will not serve as

segmentation variable; however, we will strive to have a mix of genders in each focus group. Participants will be recruited from areas throughout the United States and screened by telephone (see Attachment A – Participant Screener).

Table 1. Composition of the Focus Groups

Group	Group Demographic Characteristics	Education Level
Group 1	Hispanic	Higher Education
Group 2		Lower Education
Group 3	Non-Hispanic Black	Higher Education
Group 4		Lower Education
Group 5	Non-Hispanic Asian	Higher Education
Group 6		Lower Education
Group 7	Non-Hispanic American Indian/Alaska Native	Higher Education
Group 8		Lower Education
Group 9	Non-Hispanic Native Hawaiian/Pacific Islander	Higher Education
Group 10		Lower Education
Group 11	Non-Hispanic White	Higher Education
Group 12		Lower Education

4. How the Information is Collected

[X] Focus Group
[ ] Interview

Recruitment Information

All recruitment will be conducted by PRC Corp. (PRC), a professional focus group recruiting company subcontracted by Westat. Recruitment strategies for these companies include outreach to their proprietary databases and ad placement in local media outlets such as newspapers and local Craigslist sites and on bulletin boards at local grocery stores and restaurants. Content for the advertisement flyer can be found in Attachment B.

PRC will provide all necessary information and instructions to online focus groups participants to ensure successful login into the Zoom Webinar platform on the agreed date and time. Westat will oversee recruitment. PRC recruiters will ensure that eligible participants show up for their scheduled time slot by sending confirmation (Attachment C) and reminder correspondences (Attachment D) to participants. Participants will also receive a copy of the informed consent (Attachment E) in one or more of these correspondences from PRC and will be instructed to review the form prior to their scheduled focus group.

Twelve focus groups will be conducted. PRC will recruit eight participants per group; however, only select five to six will participate in the discussion, and the remaining participants will be dismissed.

Focus Group Discussions

A trained Westat senior social science researcher will serve as the moderator for all focus groups. Prior to beginning each discussion, the moderator will review key elements of the informed consent form (Attachment C) and answer any questions participants may have about their rights. The moderator will then use the attached moderator's guide (Attachment F) to ensure that all relevant topic areas are addressed. First, participants will be asked about their experiences with ADEs, including whether they told anyone about the event and if they filed a MedWatch report. Then, we will show participants selected items from MedWatch Form 3500B (please see screenshots included in Attachment F) to obtain their reactions to each, including their understanding of what the question is asking the reporter to do, if they would complete each question (and if not, why not), and if they would then continue to complete the form (and if not, why not).

At the conclusion, focus group observers may ask participants (via the moderator) additional ad-hoc questions. These questions are not included in the moderator's guide as they are clarifying probes linked to what the participants said during the focus group discussion.

Prior to beginning the discussion, the moderator will ensure that the FDA project director and other project team members are able to observe all the sessions via the Zoom Webinar platform. The streaming technology will allow the contractor to produce both audio and video recordings of each group, as well as provide a near-verbatim transcript of each discussion, to ensure that participants' views and opinions are accurately captured. These transcripts will form the basis of the data analysis.

Westat and PRC will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. Participants' last names will not appear on any materials shared with FDA (e.g., recruitment updates) and will be removed from participant screen names upon entry into the Zoom Webinar platform. Verbatim quotes included in the final report will not be attributed to any individual.

5. Confidentiality of Respondents

Participation / nonparticipation is completely voluntary, and participant responses will not affect their eligibility to receive any FDA services. In instances where respondent identity is needed (i.e., to contact participants who are having difficulty with their technology during the focus group), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.

6. Amount and Justification for Proposed Incentive

Participants will receive a gift card of $75 as a token of appreciation for participation in the focus group (approximately 60 minutes). Justifications for the dollar amount in compensation are included below:

- *Improved coverage of specialized respondents or rare groups.* A finite number of consumers meet the eligibility requirements for this study. The use of adequate incentives can help improve coverage of hard-to-reach populations. Our proposed sample includes a

specialized population: racial and ethnic minority consumers who have experienced an ADE.

- *Racial and ethnic minorities are a challenging and unique population to reach.* Participation in research studies can create barriers, especially to economically disadvantaged populations, due to the time commitment required to participate in research. Considering the socioeconomic status associated with racial and ethnic minorities, those barriers impact recruitment efforts of hard-to-reach populations.[1] Researchers argue that participation in research can burden the individual participant if there is no reimbursement for their efforts and compensation. Incentives ensure the participant is not left financially worse due to their participation in the research study. The Council for International Organizations of Medical Sciences as well as FDA and the office of Human Research Protections support compensating research participants for expenses incurred due to their contribution to research studies (e.g., costs of child or elder care, transportation, and meals). Fair compensation encourages the participation of lower socioeconomic status individuals including those from racial and ethnic populations and provides just compensation for their time and effort.[2,3]

- *Providing compensation for participants' effort rather than an unjust inducement*.[4,5] The proposed study poses minimal to no risk to individuals participating in the focus groups. However, the amount of time required for the focus groups to obtain sufficient data takes up a significant portion of a participant's day. Thus, the incentive of $75 is an appropriate amount for this study as discussed above. If the incentive is not adequate, participants may initially agree to participate and then fail to appear for the scheduled time, resulting in incomplete data collection and potential loss of government funds associated with recruitment costs and moderator time.[6] Moreover, if there is no monetary incentive, it is less likely that individuals will consider participating in research studies, which may result in insufficient data collection and longer recruitment periods.[7,8,9]

  – In two randomized clinical trials, financial incentives increased trial enrollment in one of the two trials and did not produce undue or unjust inducement or other unintended consequences in either trial.[10] Financial incentives are a valuable option that promote participation in research studies, especially when determination of compensation is based on the cost and effort expended by the participant as a form of respect and just reward for their participation. Use of financial incentives can enhance enrollment,

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[1]Bierer BE, White SA, Gelinas L, and Strauss DH, 2021, Fair Payment and Just Benefits to Enhance Diversity in Clinical Research, J Clin Transl Sci, 5(1): e159. doi:10.1017/cts.2021.816.
[2]Ibid.
[3]Gelinas L, Largent EA, Cohen IG, Kornetsky S, Bierer BE, Fernandez LH, 2018, A Framework for Ethical Payment to Research Participants, N Engl JMed, 766–771, doi: 10.1056/NEJMsb1710591.
[4]See footnote 1.
[5]Halpern SD, Chowdhury M, Bayes B, Cooney E, Hitsman BL, Schnoll RA, et al., 2021, Effectiveness and Ethics of Incentives for Research Participation: 2 Randomized Clinical Trials, JAMA Intern Med, 181(11):1479–1488, doi:10.1001/jamainternmed.2021.5450.
[6]Morgan, DL and AU Scannell, 1998, Planning Focus Groups, Thousand Oaks (CA): Sage Publications.
[7]Phillips T, 2011, Exploitation in Payment to Research Subjects, Bioethics, 25(4):209–219.
[8]Roche E, King R, Mohan HM, Gavin B, McNichols F, 2013, Payment of Research Participants: Current Practice and Policies of Irish Research Ethics Committees, J Med Ethics, 39(9):591–593.
[9]Wilkinson M, Moore A, 1997, Inducement in Research, Bioethics, 11(5):373–389.
[10]Ibid.

without undue coercion of any particular population, and can serve as a means to equalize study participation.[11]

– A national survey of IRB members and staff concluded that "excessively expansive or inconsistent views about coercion and undue influence held by IRB members and human subjects professionals may interfere with the recruitment of research participants by needlessly limiting the payments offered to them and may thereby impede valuable research without true cause."[12]

7. Questions of a Sensitive Nature

Participants will be asked if they have experienced an ADE but will be told explicitly that they do not need to describe the symptoms they experienced or discuss the health condition for which they are taking certain drugs. There will be no other questions of a sensitive nature asked of participants.

8. Description of Statistical Methods

This is a qualitative study using a convenience sample. It does not use statistical methods. The information gathered will be qualitative in nature, focusing on participants' perceptions of, attitudes about, and access to adverse event reporting using MedWatch. The findings will be reported as qualitative summaries using such qualitative descriptors as *most*, *many*, and *some*.

9. Burden

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Screener	150	6 minutes (0.1 hour)	15
Confirmation Letter	72	1 minute (.02 hour)	1.44
Reminder Letter	72	1 minute (.02 hour)	1.44
Informed Consent Form	72	5 minutes (.08 hour)	5.76
Setting up/Testing Technology	72	15 minutes (.25 hours)	18
Focus Group Participation Adults 18+	72	60 minutes (1 hour)	72
Total	**150**		**113.64**

10. Date(s) to be Conducted and Locations

[11]See footnote 1.

[12]Largent E, Grady C, Miller FG, Wertheimer A, 2013, Misconceptions About Coercion and Undue Influence: Reflections on the Views of IRB Members, Bioethics, 27(9):500–507.

Focus groups will take place late April through early June, 2024.

11. Requested Approval Date April 2024

12. FDA Contacts

Program Office Contact	FDA PRA Contact
Kemi Asante, Principal Investigator 301-796-7425 Center for Drug Evaluation & Research	Amber Sanford Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations