# FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

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:** Focus Groups on Childhood Obesity with Hispanic Primary Caregivers

## DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, "Focus Groups on Childhood Obesity with Hispanic Primary Caregivers."

Research shows that children from low-income backgrounds have a higher rate of overweight status compared to those who were not low-income.[1] Additionally, lower income parents are less likely to perceive their children as overweight, and more likely to experience barriers to accessing and purchasing healthy foods for their families.[2,3] Research also indicates that children from minority groups, such as Hispanics, are more likely to be overweight.[44]

The FDA Office of Minority Health and Health Equity (OMHHE) is collaborating with CFSAN to conduct this study among low-income Hispanic primary caregivers, as this meets two of their main mission objectives, namely:

- To strengthen FDA's ability to respond to minority health concerns
- To promote health and safety communication to minority populations who often experience low health literacy and/or speak English as a second language

To this end, the purpose of this focus group study is to better understand the behaviors and challenges lower income caregivers, especially Hispanic lower income caregivers, face regarding how to feed their children healthfully to understand how to best frame targeted messaging about childhood obesity. The study will investigate: (1) lower income caregivers' experiences related to making healthful food choices for their family at the

[1] Rogers, R., Eagle, T. F., Sheetz, A., Woodward, A., Leibowitz, R., Song, M., … Eagle, K. A. (2015). The Relationship between Childhood Obesity, Low Socioeconomic Status, and Race/Ethnicity: Lessons from Massachusetts. Childhood Obesity, 11(6), 691–695. http://doi.org/10.1089/chi.2015.0029

[2] Hansen AR, Duncan DT, Tarasenko YN, et al. Generational shift in parental perceptions of overweight among school-aged children. Pediatrics 2014;134:481–488

[3] Powell LM, Slater S, Mirtcheva D, et al. Food store availability and neighborhood characteristics in the United States. Prev Med 2007;44:189–195

[4] Lutfiyya, M. N., et al. (2008). "Overweight and obese prevalence rates in African American and Hispanic children: an analysis of data from the 2003–2004 National Survey of Children's Health." The Journal of the American Board of Family Medicine 21(3): 191-199.

grocery store, and at home; (2) lower income caregivers' attitudes and perceptions related to childhood obesity; and (3) lower income caregivers' identified barriers to resources to overcome childhood obesity.

2. **Intended use of information:**

The qualitative information collected from this study will contribute to the existing science knowledge foundation, which can then be used to inform future targeted education and outreach efforts.

3. **Description of respondents:**

A total of 12 focus groups are planned. Groups will include only adults (18+). All groups will include primary caregivers of one or more children between the ages of 3 and 6 years. The study will enroll participants who reside in Texas, specifically in the regions of El Paso, San Antonio, Houston, and Austin. Participants must live in or close to census tracts designated by USDA as "low access" and "high access" to supermarkets.[5] Since children from low-income families bear a disproportionate burden of obesity prevalence, the groups will include adults living in households with a size-adjusted income that is under 200% Federal Poverty Level (FPL)[6]. The groups will be segmented by race/ethnicity: Non-Hispanic White, English-Speaking Hispanic, Spanish-Speaking Hispanic. No more than 10 participants will participate in a group (see Appendix I, Participant Screener). FDA has contracted with Westat to conduct these in-person focus groups.

4. **Date(s) to be conducted and location(s):**

Focus groups will be conducted approximately one month from the date of OMB approval. The focus groups will be conducted in El Paso, TX; San Antonio, TX; Houston, TX; and Austin, TX. These locations were chosen because of their prevalence of childhood obesity and their proximity to census tracts of low access to supermarkets and high access to supermarkets[7]. The selected locations offer suitable focus group facilities and recruitment capabilities that will enable us to recruit groups of ethnically diverse, low-income participants who meet the criteria described in section 3 above.

5. **How the Information is being collected:**

<u>Recruitment Information</u>

Staff from the focus group facilities will use their in-house databases to recruit participants via telephone using the participant screener (Appendix I). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will ensure that the needed

[5] Economic Research Service (ERS), U.S. Department of Agriculture (USDA). Food Access Research Atlas, https://www.ers.usda.gov/data-products/food-access-research-atlas

[6] Castner, L, and Mabli, J. (2010). Food Expenditures and Diet Quality Among Low-Income Households and Individuals. The report was prepared by Mathematica Policy Research for the Food and Nutrition Service. This report is available online at www.fns.usda.gov/ora https://www.cdc.gov/obesity/data/childhood.html#Prevalence of Childhood Obesity in the United States, 2011-2014

[7] https://www.cdc.gov/mmwr/volumes/65/wr/mm6545a2.htm?s_cid=mm6545a2_w

number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants. For those focus groups held in community centers, Westat will liaise with community leaders to recruit and confirm participants.

Focus Group Discussions

Westat staff members will serve as moderators for all focus groups. FDA staff members will observe most, if not all, of the sessions from the observation rooms at the focus group facilities, in-person in community-held focus groups, or remotely using streaming technology.

The moderator will use the attached Moderator Guide (Appendix II) to ensure that all relevant topic areas are addressed. The focus group facilities will make audio and video recordings (as available) to ensure a verbatim record of the proceedings is captured.

The Contractor will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. **Number of focus groups:**

A total of 12 focus groups of 8 to 10 participants will be conducted.

7. **Amount and justification for any proposed incentive:**

To prepare for these focus groups, we consulted with facilities that recruit and host focus groups to determine appropriate amounts as tokens of appreciation. Based on these consultations, we propose offering $75 for 90 minutes as a token of our appreciation to ensure that we are able to attract a reasonable cross section of participants who earn household incomes within our preferred range.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the commonly accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment;
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants); and
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs, but also puts additional burden on the recruited participants who have to reschedule their participation in the focus group.

Our proposed incentive amount will help ensure that respondents honor their commitment of participating in the focus groups. Our incentive was chosen based on: (1)

an estimated cost related to childcare for 3 hours (e.g., approximate travel time to and from facility, time to park a vehicle, check-in and check-out procedures, and the 90-minute focus group discussion), which is approximately $48[8]; (2) an estimated cost for an average driving commute to and from the facility of approximately $18[9]; and (3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.[10] The proposed amount is comparable to what has been the level of reimbursement for the target audiences in similar government-funded activities. Parents of young children are often more difficult to recruit than more general audiences and the incentive needs to be enough to help the participants cover outside childcare costs if needed. As noted above, we expect that lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

The importance of monetary compensation for focus group participation has been discussed by Krueger and Casey (2014), who indicate that offering minimal levels of monetary compensation can help ensure that sufficient numbers of participants will attend, thereby yielding more useful research results.[11] Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups.[12] When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation and treats them justly and with respect by recognizing and acknowledging the effort they expend to participate.[13] Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)[14] and internal proprietary research conducted by our contractor.

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

There will be no questions of a sensitive nature asked of participants.

9. **Description of statistical methods (i.e., sample size & method of selection):**

This study employs qualitative methods and does not entail the use of any statistical methods.

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[8] Assumes an hourly rate of $16 per hour for a professional babysitter

[9] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf

[10] See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal*, *16*(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.

[11] Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.

[12] Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79.

[13] Halpen, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine*, *164*(*7*), 801-803.

[14] Berlin, M., L. Mohadjer, J. Waksberg, A. Kolstad, I. Kirsch, D. Rock, & K. Yamamoto. An experiment in monetary incentives. American Statistical Association, Proceedings of Survey Research Methods Section; Alexandria, VA: 1992. pp. 393–398.

**BURDEN HOUR COMPUTATION** *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Table 1 shows the estimated annual reporting burden for the groups, assuming 10 participants per group.

**Table 1.**

| Type/Category of Respondent | No. of Respondents | Participation Time (minutes) | Burden (hours) |
|---|---|---|---|
| Screener | 600 | 5 | 50 |
| Focus group discussion | 144 | 90 | 216 |
| Total | | | 266 |

**REQUESTED APPROVAL DATE:** February 17, 2020

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