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 Education (Formative Research)

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 Education (Formative Research)."

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]

On March 29, 2018, FDA Commissioner Gottlieb outlined the ways in which FDA can contribute to the ongoing efforts of mitigating chronic diseases, including those affected by poor diet and nutrition. As it pertains to obesity, Commissioner Gottlieb highlighted the importance of improving the nutrition and diet of Americans, noting that the prevalence of obesity in children increased from 16.8% in 2007-2008 to 18.5% in 2015-2016. Also cited in the speech was the statistic that "while 97 percent of American parents believe that childhood eating habits determine children's health for their lifetime, only 17 percent say their child's diet is very healthful, according to the National Poll on Children's health. That same survey also found that nearly half of all parents have difficulty determining which foods are actually healthy." Commissioner Gottlieb also underscored the importance of understanding the disproportionate needs of vulnerable populations, highlighting those from lower socioeconomic backgrounds and those who have little to no access to supermarkets.[4]

To this end, the purpose of this focus group study is to better understand the behaviors and challenges lower income caregivers have regarding how to feed their children healthfully, and to understand how to best frame targeted messaging about childhood

[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] Gottlieb, S. (2018). *Reducing the Burden of Chronic Disease*. White Oak, MD: https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm

obesity. The study will investigate (1) lower income caregivers' experiences related to making healthful food choices for their family at the grocery store, home, and at restaurants; (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 campaign 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 the Washington, DC metro area; Baltimore, MD; Dallas, TX; and Austin, TX and 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 300% Federal Poverty Level (FPL)[6]. Some groups will be segmented by race/ethnicity that matches the demographic makeup of the selected locations. No more than 10 participants will participate in a group (see Appendix I, Participant Screener). FDA has contracted with Fors Marsh Group (FMG) 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 Arlington, VA/Washington, DC; Baltimore, MD; Austin, TX; and Dallas, TX. These locations were chosen because of their high 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

[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

proper location on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

FMG 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 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 to ensure a verbatim record of the proceedings is captured.

The Contractor will comply with safeguards for ensuring participant information is kept private 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 for participants' time. Based on these consultations, we propose $75 for 90 minutes 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)
- 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 group 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, FMG.

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

None.

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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.

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

The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (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 conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. This study employs qualitative methods and does not entail the use of any statistical methods.

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

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

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	600	5	50
Focus group discussion	144	120	288
Total			338

REQUESTED APPROVAL DATE: July 13, 2018

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