# 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 with Nutrition Educators

#### 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 with Nutrition Educators".

The Food and Drug Administration (FDA) develops education initiatives aimed at helping consumers interpret and incorporate nutrition information in the context of their daily lives. The effectiveness of such efforts relies heavily on the delivery of nutrition education information by professionals, such as nutrition educators.

To support and further improve the effectiveness of FDA's nutrition education initiatives, FDA is planning to conduct this focus group study to better understand nutrition educators' concerns and lessons learned through their work, and to identify ways that FDA can support their educational efforts. Results of this study will provide the Center with an in-depth understanding of the needs and challenges faced by nutrition educators, what approaches and resources they find most helpful and would prefer to use when providing information to the population they serve, and how FDA can best support their activities.

This research aligns with FDA's Center for Food Safety and Applied Nutrition (CFSAN) strategic goal to "advance diet and health research that contributes to the development of science-based policies and communication strategies" and is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

## 2. Intended use of information:

As stated above, by obtaining a better understanding of the challenges nutrition educators face, this study serves to help the agency identify gaps in current communication strategies and to further assist with formulating effective educational materials.

### 3. **Description of respondents:**

FDA has contracted with RTI International to conduct a total of 20 focus groups.

Groups will include only adult individuals (18+) who currently work as nutrition educators. Groups will be segmented by (1) nutrition educator type and (2) location; and will be conducted either in-person or virtually. Details of group segmentation and mode are provided in the table below.

| Grou<br>p# | Participants/<br>Nutrition Educator Type                       | Location       | Mode                     |
|------------|--|----------------|--------------------------|
| 1 2        |  | MD             |                          |
| 3          |  |                |                          |
| 4          |  | TX             |                          |
| 5          | Nutrition Assistance Program Educators                         | NC             | In-person                |
| 6          |  | 110            |                          |
| 7          |  | CA             |                          |
| 8          |  | CA             |                          |
| 9          |  | WI             |                          |
| 10         |  | VVI            |                          |
| 11         |  |                |                          |
| 12         | Local/County/State Department                                  |                |                          |
| 13         | Health Educators   |                |                          |
| 14         |  |                | Virtual                  |
| 15         | Geographically Grocery Store Educators  Geographically Diverse | Geographically |                          |
| 16         |  | • •            |                          |
| 17         |  |                |                          |
| 18         |  |                |                          |
| 19         | A N E J  |                | In-person (at a national |
| 20         | Any Nutrition Educators  |                | nutrition conference)    |

The groups will have a mix of genders. The in-person focus groups will contain no more than 8 participants in each group, and virtual focus groups will contain no more than 6 participants in each group. (see Appendix I, Participant Screener).

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

Given the ongoing COVID-19 pandemic, the groups will be conducted after receipt of OMB approval and when it is safe to do so.

Ten (10) of the in-person focus groups (with nutrition assistance program educators) will be conducted in Maryland, Texas, North Carolina, California, and Wisconsin. The selected locations: (1) offer suitable focus group facilities and recruitment capabilities that will enable us to recruit participants who meet the criteria described in section 3 above; and (2) partially align with FDA's planned nutrition education campaign efforts on the new Nutrition Facts label. Given the nature of this study that the participants are all nutrition educators, these in-person groups will be conducted at non-conventional facilities (e.g. cooperative extension centers/offices and local conference venues).

Two (2) of the in-person focus groups (with any type of nutrition educator) will be conducted at a national nutrition education conference – the Society for Nutrition Education and Behavior (SNEB) annual conference in 2021 (SNEB 2021, New Orleans, LA, August 7-10, 2021).

Eight (8) of the focus groups (with local/county/state department health educators and grocery store educators) will be conducted virtually and without restriction to any specific geographic location.

## 5. How the Information is being collected:

### **Recruitment Information**

RTI International will recruit participants via identifying and working with key personnel who have broad connections with nutrition educators (e.g. extension agents), using the online participant screener (Appendix I). RTI International staff will provide all necessary information and instructions to ensure participants arrive at the proper location (for in-person groups) or have the appropriate technology (for virtual groups) on the agreed upon date and time. RTI International will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot and will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

## Focus Group Discussions

An RTI International staff member will serve as moderator for all focus groups. For inperson groups, FDA staff members will observe the sessions either at the location where focus groups take place, or remotely using streaming technology, when available. For virtual groups, FDA staff members will observe most, if not all, of the sessions via the virtual focus group platform.

The moderator will use the attached moderator guide (Appendix II) to ensure that all relevant topic areas are addressed. RTI International will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

RTI International 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 20 focus groups with 6-8 participants in each will be conducted.

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

To prepare for these focus groups, we consulted with the Contractor (RTI International) on their past experience with similar studies to determine appropriate amounts as tokens

of appreciation. Based on these consultations, we propose offering a \$50 incentive, as a token of our appreciation, to ensure that we are able to attract a reasonable cross section of participants.

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 groups. The proposed amount was chosen based on: (1) participants spending approximately 2-3 hours of their time on this effort (including: time spent for online screening and the 90-minute focus group discussion for all groups; time for traveling to and from the location where the focus group takes place, time to park a vehicle, and check-in and check-out procedures for in-person groups; time for testing the platform, the request to log in 15 minutes early to confirm technical operation for virtual groups); and (2) the Bureau of Labor Statistics' (BLS) calculation of the average hourly wage of employees on education and health services payrolls in June 2020, which is \$28.41 (Bureau of Labor Statistics, 2020).

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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> Finally, the importance of monetary incentives has

<sup>&</sup>lt;sup>1</sup> Bureau of Labor Statistics, U.S. Department of Labor, Economic News Release, on the Internet at <a href="https://www.bls.gov/news.release/empsit.t19.htm">https://www.bls.gov/news.release/empsit.t19.htm</a> (visited July 6, 2020).

<sup>&</sup>lt;sup>2</sup> Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.

<sup>&</sup>lt;sup>3</sup> Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79.

<sup>&</sup>lt;sup>4</sup> 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.

been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)<sup>5</sup> 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.

**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 8 participants per in-person group and 6 participants per virtual group.

Table 1.

| Type/Category of<br>Respondent | No. of<br>Respondents | Participation<br>Time (minutes) | Burden<br>(hours) |
|--------------------------------|-----------------------|---------------------------------|-------------------|
| Screener                       | 600                   | 5                               | 50                |
| Focus group discussion         | 144                   | 150                             | 360               |
| Total                          |                       |                                 | 410               |

**REQUESTED APPROVAL DATE:** August 20, 2020

#### NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi (PRA Analyst) <u>Ila.Mizrachi@fda.hhs.gov</u> 301-796-7726

Fanfan Wu (Program Contact) <u>Fanfan.Wu@fda.hhs.gov</u> 240-402-1808

**FDA CENTER:** Center for Food Safety and Applied Nutrition (CFSAN)

<sup>&</sup>lt;sup>5</sup> 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.