

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

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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:** Food Safety Focus Groups

## **DESCRIPTION OF THIS SPECIFIC COLLECTION**

### **1. Statement of need:**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, "Food Safety Focus Groups". These focus groups were already approved with an ICR Reference number: 201406-0910-019 on 11/24/2014. However, due to changes in the agency priorities and needs, the groups were not conducted and the burden hours were not used. We have therefore redesigned the moderator's guide and screener to meet FDA and USDA's current food safety goals. We are planning to change the topics covered in the focus group discussion guide from consumer behaviors and knowledge of thermometer use and fruit and vegetable washing, to knowledge and behaviors related to restaurant inspection scores, consumer advisories about the risks of eating raw and undercooked animal foods in restaurants, and use of devices such as smart phones and tablets in the kitchen while cooking. We are requesting that the previously approved 192 burden hours plus an additional 40 hours for recruitment be used for this revised project.

### **2. Intended use of information:**

The Food Code represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government.

Within the Food Code, FDA provides recommendations on how certain information should be communicated to the consumer. For example, the FDA Food Code includes a provision stating retail food establishments are to inform consumers of the significantly increased risk of consuming raw or undercooked animal foods by way of a disclosure of the presence of a raw or undercooked animal food in a menu item, and a reminder about the risks associated with consumption of raw or undercooked animal foods. The Food Code also includes provisions describing how restaurant inspectional information should be made available to the public.

As the retail food industry rapidly evolves and changes, and as consumer preferences change, it is important for FDA to periodically talk with consumers to better understand how they receive, interpret, and react to this information. The focus group results will be used by FDA to stimulate internal discussions about the current recommendations in the Food Code and identify potential opportunities for enhancing the mechanisms through which this information is provided to consumers.

We also plan to ask about how and when consumers use devices such as tablets and smart phones while cooking as a follow-up to questions asked on the most recent Food Safety Survey. On the survey, we found about half of consumers reported using devices while cooking. Of those who use devices while cooking, only about a third reported washing their hands after touching their device before they continue cooking. This is much lower than the self-reported hand washing behavior after touching raw eggs, meat, chicken, or fish. While the survey data are very helpful for assessing consumers' knowledge, attitudes, and beliefs about food safety they do not provide a complete understanding of why consumers do or do not engage in certain behaviors. We would like to explore this topic in these groups and see how consumers would respond to messages about washing hands while using devices in the kitchen.

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

A total of eight focus groups are planned. All of the participants must be at least 18 years old, must have eaten at a full service restaurant at least once in the past month, must prepare the main home meal at least some of the time, and have used a cell phone, tablet, or laptop when cooking. Additionally, half of the groups will be with participants who have some college or higher and half with those who have lower levels of education. Within these groups there will be a mix of genders, ages, and races/ethnicities. We will recruit 12 participants for each group, and expect to have 8 to 10 participants per group. No more than 12 participants will participate in a group. To recruit the total number of participants in all groups, we expect to target 480 initial respondents in our prescreening effort. (See Appendix I).

### **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 four locations: Washington, DC (metro area), Southeast, Mid-West, and West. We plan on choosing locations that have a restaurant scoring, grading, or placarding system in place and have requirements for alerting consumers to the risks of eating undercooked foods on menus.

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

#### Recruitment Information

Staff from an independent contractor will use their in-house databases to recruit participants via telephone using the participant screener (Appendix I). The contractor's staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. The independent contractor will conduct recruitment and ensure that the needed number of participants arrive for their scheduled time slot. The independent contractor will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

#### Focus Group Discussions

With the aid of a moderator's guide (see Appendix II), a moderator supplied by the independent contractor will guide the focus group discussions that will solicit information from the participants. The focus group discussion will be recorded and transcripts will be made from these recordings. Transcripts and notes taken by the project staff will be the bases for data analysis. Transcripts and notes will be used to analyze data.

## **6. Number of focus groups:**

A total of eight focus groups will be conducted.

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

In preparation for these focus groups, we consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose an incentive of \$75 for approximately 120 minutes to ensure that we are able to attract a reasonable cross section of participants who meet our screening requirements.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the 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<sup>1</sup>; 2) an estimated cost for an average driving commute to and from the facility of approximately \$18<sup>2</sup>; 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.<sup>3</sup> The proposed amount of \$75 is comparable to what has been the level of reimbursement for the target audiences in similar government funded activities. 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.

## **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):**

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<sup>1</sup> Assumes an hourly rate of \$16 per hour for a professional babysitter

<sup>2</sup> Assumes travel by automobile; calculation derived from average annual commuting costs reported at [https://www.census.gov/hhes/commuting/files/JSM\\_Proceedings\\_paper.pdf](https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf)

<sup>3</sup> 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.

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix I). To maximize participation rates participants will receive a reminder call and confirmation letter before the groups convene.

Table 1 shows the estimated annual reporting burden for the groups, assuming 12 participants per group.

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

**Table 1.**

<b>Type/Category of Respondent</b>	<b>No. of Respondents</b>	<b>Participation Time (minutes)</b>	<b>Burden (hours)</b>
Screener (Adults age 18 and older)	480	5	40
Focus Group Discussion (Adults age 18 and older)	96	120	192
<b>Total</b>			<b>232</b>

**REQUESTED APPROVAL DATE:** August 1, 2016

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