

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS & IN-DEPTH INTERVIEWS FOR THE FDA CDER RISK COMMUNICATIONS INITIATIVE (0910-0497)

TITLE OF INFORMATION COLLECTION: Spousal Influence on Consumer Understanding of and Response to DTC Prescription Drug Advertisements (Formative Research and Stimuli Testing)

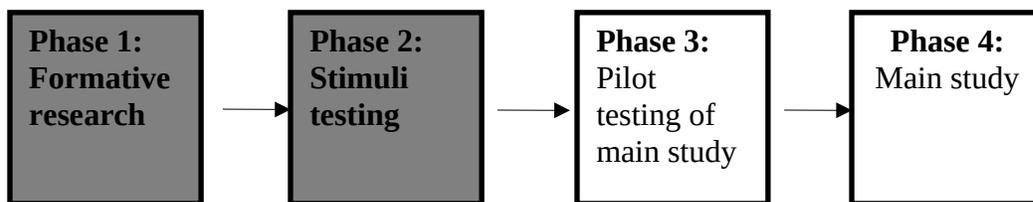
DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) is seeking OMB approval under the generic clearance 0910-0497 for the focus group / interview project, “Spousal Influence on Consumer Understanding of and Response to DTC Prescription Drug Advertisements (Formative Research and Stimuli Testing).”

Consumer understanding of direct-to-consumer (DTC) prescription drug advertisements and subsequent medical decisions are likely influenced by the conversations and interactions consumers have with important people in their lives. A spouse or partner can help frame the risks and benefits portrayed by health messages. In addition, spouses have to coordinate behaviors to manage health conditions. The available literature does not provide clear empirical results highlighting all key processes that may occur between spouses and consumers regarding prescription drug advertisements. As a result, we will conduct formative research and stimuli testing. Exhibit 1 illustrates the full set of research phases that we intend to conduct; note, however, that this information collection request concerns the highlighted formative research and stimuli testing phases only.

Exhibit 1. Overview of Research Phases



The formative research (Phase 1) will help us to assess: 1) how couples discuss medications and make medication decisions; 2) whether they discuss DTC prescription drug ads and under what circumstances; 3) characteristics of discussion (e.g., who initiates, what they say to each other); and 4) influence of discussion on perceptions about the medication and medication decision making. Focus group discussions will explore the various ways in which spouses influence consumer decision making, and from the consumer perspective, how spouses influence them and what aspects of influence and support they find most helpful.

The stimuli testing (Phase 2) will allow us to gather feedback on draft stimuli (fictional TV ads) we are developing. Focus group questions will specifically probe for information on whether

participants would be likely to talk with a spouse/partner about the ad, what aspects of the ad they would be likely to discuss, and other considerations. As part of Phase 2, we will also conduct dyad interviews with couples to observe conversations about the test stimuli. These interviews will help us to develop a content coding scheme to be used in later phases of the research.

2. Intended use of information:

In recognizing the potential role of caregivers in consumers’ medical beliefs, decisions, and behaviors, this set of focus groups and interviews will examine spousal influence on consumer understanding of and response to DTC prescription drug advertising. This information collection request involves two qualitative phases of research that will be used to inform part of a larger quantitative project on the same topic, to be submitted for approval at a later time.

3. Description of respondents:

Both Phase 1 (formative research, see Exhibit 2) and Phase 2 (stimuli testing, see Exhibit 3) involve six focus groups each – three with consumers and three with spouses. Each focus group will consist of 8 people and will last 90 minutes. As part of Phase 2, we will also conduct 14 dyad interviews with couples. These interviews will also last 90 minutes. Focus groups and interviews will be held in the Raleigh, NC and Washington, D.C. metro areas. FDA contracted with RTI International to conduct these in-person focus groups and interviews.

Exhibit 2. Formative Research Design

Location	Focus Groups		TOTAL
	Consumers	Spouses	
Raleigh, NC (Groups 1–3)	2 groups	1 group	3 groups
Washington, DC (Groups 4–6)	1 group	2 groups	3 groups
TOTAL	3 groups	3 groups	6 groups (8 per group, N = 48)

Exhibit 3. Stimuli Testing Design

Location	Focus Groups		Dyad Interviews	TOTAL
	Consumers	Spouses	Consumer-Spouse	
Raleigh, NC (Groups 1–3)	1 group	2 groups	7 dyads	3 groups 7 dyads
Washington, DC (Groups 4–6)	2 groups	1 group	7 dyads	3 groups 7 dyads
TOTAL	3 groups	3 groups	14 dyads	6 groups (8 per group, n = 48); 14 dyads (n = 28) Total N = 76

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

Focus groups and interviews will be conducted in the metropolitan areas of Raleigh, NC and Washington, DC. Focus groups are planned for the Fall of 2014.

5. How the information is being collected:

Recruitment Information

Staff from the focus group / interview facilities will conduct subject recruitment using the participant screeners (attached). 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 intentionally over-recruit to ensure the minimum number of participants needed come to their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group and Interview Discussions

RTI staff members will serve as moderators for all focus groups and interviews. OPDP 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 guides to ensure that all relevant topic areas are addressed. The focus group facilities will make audio 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 / interview materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. Number of focus groups:

Formative research: 6 focus groups

Stimuli testing: 6 focus groups, 14 interviews

See Exhibits 2 and 3 for greater detail.

7. Amount and justification for any proposed incentive:

In preparation for these focus groups, RTI consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose an incentive of \$75 to ensure that we are able to attract a reasonable cross-section of general population participants.

Our experience in conducting focus group research indicates that offering 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. This incurs additional costs and puts additional burden on the recruited participants who have to reschedule their participation in the focus group

Furthermore, there is some evidence that using incentives can actually reduce nonresponse bias in some situations by bringing in a more representative set of respondents.^{1,2,3} This may be particularly effective in reducing nonresponse bias due to topic saliency.⁴

8. Questions of a sensitive nature:

None.

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

- 1 Castiglioni, L., & Pforr, K. (2007). The effect of incentives in reducing non-response bias in a multi-actor survey. *Presented at the 2nd annual European Survey Research Association Conference*, Prague, Czech Republic, June, 2007.
- 2 Singer, E. (2002). The Use of Incentives to Reduce Nonresponse in Household Surveys. (R. M. Groves, D. A. Dillman, J. L. Eltinge, & R. J. A. Little, Eds.) *Survey nonresponse*, (051), 163-178. University of Michigan Institute for Social Research. Retrieved from <http://www.isr.umich.edu/src/smp/Electronic>.
- 3 Singer, E. (2006). Nonresponse bias in household surveys. *Public Opinion Quarterly*, 70(5), 637-645.
- 4 Groves, R., Couper, M., Presser, S., Singer, E., Tourangeau, R., Acosta, G., & Nelson, L. (2006). Experiments in producing nonresponse bias. *Public Opinion Quarterly*, 70(5), 720-736.

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 intentionally over-recruit to ensure the minimum number of participants needed come to their scheduled time slot.

Table 1 shows the estimated annual reporting burden for the groups, assuming 8 participants per group.

Table 1: Estimated Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)	Total Hours
Formative Research (Phase 1)					
Number to complete the screener	180	1	180	0.03 (2 minutes)	5.4
Number of completes	48	1	48	1.5	72
Stimuli Testing (Phase 2)					
Number to complete the screener	180	1	180	0.03 (2 minutes)	5.4
Number of completes	48	1	48	1.5	72
Stimuli Testing – Dyads (Phase 2)					
Number to complete the screener	180	1	180	0.08 (5 minutes)	14.4
Number of completes	28	1	28	1.5	42
TOTAL HOURS					
211.2					

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

REQUESTED APPROVAL DATE: October 1, 2014

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