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 Group Testing of Consumer Messaging on Participation of Diverse Women in Clinical Trials

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   Section 907 of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) required FDA to draft a report and action plan on the participation of demographic subgroups in clinical trials submitted to FDA in support of product applications. FDA released the Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data in August 2014. The Action Plan includes a campaign to be coordinated by FDA Office of Women's Health (FDA OWH) to raise awareness about the importance of participation of diverse women in clinical trials.

   To fulfill the FDASIA Section 907 Action Plan requirement and address increased public interest related to clinical trials, the FDA OWH proposes conducting a series of three (3) focus groups to obtain consumer feedback on the readability and usability of the FDA OWH 'Women in Clinical Trials' fact sheet and to learn more about consumer knowledge and opinions about clinical trials. The consumer fact sheet was developed in 2003 to provide general information on clinical trials and important risks and benefits women should consider before joining a trial. The fact sheet was approved by DHHS in 2003 and is available on the FDA website.

   FDA OWH would like to update the fact sheet and other web-based messaging related to the participation of women in clinical trials. The focus groups would provide feedback from women in the real world about the topics and questions they would most like to see in the fact sheet and provide insight into the information sources and potential distribution channels that would be most effective in disseminated the FDA OWH information to women. The focus groups will be conducted by Bixal Solutions, Inc. – a Contractor for the FDA Office of Women's Health

2. **Intended use of information:**
   The information gathered in the focus groups will be used to refine the messaging and layout of the FDA OWH print and electronic resources on women in clinical trials.

3. **Description of respondents:**
   The participants will be women between the ages of 21 and 65 from diverse racial/ ethnic backgrounds, income levels, and health statuses.

4. **Date(s) to be conducted and location(s):**
   One focus group will be conducted in Rockville, MD on July 29, 2015 (Back-up date: August 20, 2015). One focus group will be conducted in Dallas, TX on August 20, 2015

(Back-up dates: September 1 or 2, 2015). One focus group will be conducted in Los Angeles, CA on August 27, 2015 (Back-up date August 27, 2015). Dates are tentative pending approval and facility availability.

5. How the Information is being collected:

The attached participant screener, prepared by FDA OWH, will be used by the Contractor to recruit the focus group participants. Participants are recruited two to three weeks prior to the focus group. The Contractor will work with a market research facility in each city to coordinate recruitment. Participants will be recruited from the facility's database of individuals, households, community organizations, independent clubs, and activity-centered groups in the local area. The facility may also contact (via email or telephone) community organizations, clinics, and other groups in the local area to request that recruitment flyers be hung in their facilities. Potential participants will be contacted via telephone, and the recruiter will read through the attached screener to determine eligibility. Participants are sent confirmation emails immediately after they are recruited. They are asked to reply to the email with a confirmation that they will participate. Follow-up telephone calls are also used to confirm participation. A total of 75 women will be screened to ensure that there are between 5-8 eligible participants in each focus group.

The focus groups will be held at the following independent market research locations.

Eureka Facts - 51 Monroe Street, Plaza East 10 Rockville, MD 20850

Plaza Research - 14160 Dallas Parkway, Suite 602, Dallas, TX 75254

Plaza Research - 6053 W Century Blvd # 100, Los Angeles, CA 90045

If focus group clearance is not obtained by late July 2015, then the focus group locations may have to be changed pending availability of the research locations.

The attached moderator's guide, prepared by FDA OWH, will be used by the Contractor to facilitate the guided discussion. A trained facilitator will moderate the focus group discussions. Discussion begins on or near the prearranged time, when most or all of the participants have arrived. After short introductions, the moderator eases the participants into a discussion of the specific topics related to the materials being tested. The facilitator does not pose any questions of a sensitive or private nature. The moderator continues to facilitate the discussion until all of the topics in the moderator's guide have been addressed. Time is allowed to address ideas and questions spontaneously generated from the discussion. Reliability and validity are assessed iteratively by revisiting respondents' verbalizations and asking for clarifications. This is done both within the course of individual discussions and between separate group discussions.

Contractor and FDA staff will observe the groups in real time behind a one-way mirror. The participants will be informed that they are being observed. The groups will also be audiotaped. Before the group discussion begins, the facilitator will obtain verbal consent from the participants to audiotape the sessions. The consent forms also mention the audiotaping. The consent forms will be reviewed with each participant and signed prior to them joining the discussion group. Transcriptions of the audio recordings will be used by

the Contractor to analyze participant responses and prepare the Final Report. The focus group participants will be informed about how the tapes are used in the analyses, and assured that the recorded data are kept in a locked storage cabinet in a secure room, and that the recordings are destroyed after five years.

The Contractor will comply with additional safeguards for ensuring participant confidentiality. Participants will not have to use their last names during group discussions, and the last names will not appear on any focus group materials (typed lists of participants, name placards, transcripts, draft or final reports). Participants will also have the option of using a pseudonym. Verbatim quotes in the final report will not be attributed to an individual participant. Data will be used in the aggregate.

Focus group participants will provide their reactions to the FDA OWH fact sheet and provide suggestions as to ways the layout and messaging could be improved. The focus groups will be conducted to answer the following general questions:

- What are women's attitudes about participating in a clinical trial and where do women get information about clinical trials?

- What do women think about the readability and layout of FDA plain language materials on women in clinical trials?

- What are women's reactions to and suggestions for improving general messages that will be used in the FDA OWH outreach campaign to raise awareness about the importance of diverse women participating in clinical trials?

Following the three groups, the Contractor will listen to the audiotapes and read the transcripts for each session. The Contractor will develop an independent top line summary of each group. The Contractor will draft a report within three weeks after the completion of the last focus group, and will submit this draft report to FDA OWH for review. The report will include an Executive Summary, Key Findings, Summary and Recommendations, and Appendices. Within one week following receipt of the report, FDA OWH will forward comments on the draft to the Contractor. The Contractor will then submit the final report within five weeks after the completion of the last focus group.

6. **Number of focus groups:**
   3

7. **Amount and justification for any proposed incentive:**
   Each focus group participant will be provided a $75 incentive. The incentive is designed to offset the cost of childcare. Lack of child care has been identified as a barrier to research participation for women.

8. **Questions of a Sensitive Nature:**
   The groups will not ask any questions of a sensitive or private nature.

9. **Description of Statistical Methods (I.E. Sample Size & Method of Selection):**
   A total of 24 women will be recruited to participate to ensure that there are 6-8 women per group. Participants will be drawn from the general population of women using the

criteria stipulated in the participant screener. The contractor will work with a market research facility to use their database of potential respondents to identify participants for the focus groups.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Participant Screening	75	.08	6
Focus Group	24	1.50	36
			42

Participant Screening/ Recruitment: A total of 75 women will be screened to ensure that there are between 5-8 eligible participants in each focus group.

Focus Group: Each respondent will participate in one (1) focus group. There will be 5 minutes for informed consent and 85 minutes for group discussion.

REQUESTED APPROVAL DATE: July 24, 2015

NAME OF PRA ANALYST & PROGRAM CONTACT: PRA Specialist - Amber Sanford **/ Program Contact -** Kimberly A Thomas, MPH

FDA CENTER: Office of the Commissioner