

**FDA OFFICE OF WOMEN'S HEALTH  
Diverse Women in Clinical Trials  
Focus Group Screener Guide**

**Introduction:** Hello, I am {INTERVIEWER NAME}, and I am calling to invite women in your area to participate in a small group discussion about diverse women in clinical trials. Clinical trials help to show if medical products, tests, and other treatments are safe and effective. This discussion will be confidential and anonymous. Your name or other identifying information will not be shared with anyone outside this research project. You do not need to prepare to participate. We are interested in your opinions and comments on health education materials. You will receive \$75 for your participation and light refreshments will be provided during the discussion. May I ask you a few questions to determine if you are eligible to participate?

**Voicemail Message:** *Hi, my name is {INTERVIEWER NAME} I am calling about participating in a women's health project about diverse women in clinical trials. We will try to call you back over the next few days to see if you may be interested in participating.*

- 01 CONTINUE  
02 TERMINATE (RECORD REASON AND THANK) \_\_\_\_\_

**Questions**

1. [INTERVIEWER: INDICATE LOCATION OF FOCUS GROUP AREA]
- 1 Rockville, MD
  - 2 Dallas, TX
  - 3 Los Angeles, CA (surrounding area)
2. Is participant female? [INTERVIEWER: ASK ONLY IF NECESSARY]
- 01 Male (TERMINATE)
  - 02 Female (CONTINUE)
3. What is the highest grade or year of school you completed? [INTERVIEWER: DO NOT READ LIST]
- 01 6<sup>th</sup> grade or less (TERMINATE)
  - 02 7<sup>th</sup> grade-11<sup>th</sup> grade (CONTINUE)
  - 03 12<sup>th</sup> grade/GED (CONTINUE)
  - 04 Some college/Associate (CONTINUE)
  - 05 College graduate or higher (TERMINATE)
  - 99 Refused (TERMINATE)

4. Have you participated in a focus group in the past 6 months?

- 01 Yes (TERMINATE)
- 2 No (CONTINUE)

5. Are you comfortable reading and writing English?

- 1 Yes (CONTINUE)
- 2 No (TERMINATE)

6. Do you currently have health insurance?

- 01 Yes
- 02 No

7. Do you regularly visit a health care provider?

- 01 Yes
- 02 No

9. Have you ever participated in a clinical trial?

- 1 Yes
- 2 No

10. Have you been diagnosed with any of the following conditions? (MAY SELECT MORE THAN ONE CONDITION)

- 1 Diabetes
- 2 Lung Disease (e.g. COPD)
- 3 Heart disease (CVD)
- 4 Depression or Anxiety
- 5 Other: \_\_\_\_\_
- 6 NONE

11. How old are you? \_\_\_\_\_

[INTERVIEWER: RECORD AGE AND SELECT AGE CATEGORY. IF RESPONDENT PREFERS NOT TO PROVIDE AGE, READ THE LIST OF CATEGORIES]

- 01 18 to 20 (TERMINATE)
- 02 21 to 30
- 03 31 to 40
- 04 41 to 50
- 05 51 to 60
- 06 61 to 65
- 07 Over 65 (TERMINATE)
- 99 Refused

**12. How would you best describe yourself? [INTERVIEWER: READ LIST]**

- 01 White, non-Hispanic
- 02 Black, non-Hispanic
- 03 Hispanic/Latino
- 04 Asian, describe: \_\_\_\_\_
- 05 American Indian/Native American
- 06 Other, describe: \_\_\_\_\_
- 99 Refused

**13. Last question: please stop me when I reach the category that includes your household's total annual income for last year, 2014.**

- 01 Under \$15,000
- 02 From \$15,000 to less than \$30,000
- 03 From \$30,000 to less than \$50,000
- 04 From \$50,000 to less than \$75,000
- 05 From \$75,000 to less than \$100,000
- 06 From \$100,000 to less than \$125,000
- 07 \$125,000 or more
- 08 Don't Know
- 99 Refused

Thank you for answering the questions. We would like to invite you to participate in discussion about women in clinical trials with a small group of 5-7 other women from the {Washington DC/Dallas/LA} area on {July/Aug XX at 6pm}. Again, you will receive \$75 for your participation and it should take approximately 90 minutes of your time, if you choose to participate. Light refreshments will also be provided. During the discussion we will ask your opinion and comments and everything discussed will be confidential and anonymous. No identifying information will be used. Participation is voluntary and you may leave at any time. Would you like to participate in this group?

- 1 Yes (CONTINUE TO COLLECTING CONTACT INFORMATION)
- 2 No (THANK FOR TIME AND TERMINATE)

**INTERVIEWER: Recruit women with a variety of:**

- income levels
- target health conditions (Diabetes, Heart Disease/CVD, Lung Diseases, Depression) **also** want healthy women
- ages, and
- ethnicities

**PARTICIPANT CONTACT INFORMATION**

Thank you very much for your interest in participating. The last thing I need to ask is for contact information to send you a letter with details about participating including location/directions to the focus group on **July/Aug XX at 6pm**. We will also call before the discussion to confirm. Again, this information will be used *only* to confirm participation and will not be used for any other purposes.

Lastly, we will make every effort to accommodate persons with physical disabilities or special needs. Do you require special accommodations due to a disability?

- 1 Yes. Describe: \_\_\_\_\_
- 2 No

Respondent name _____
Telephone _____ Alternate _____
Address _____ _____
E-mail _____
Best time and way to be reached _____

**Participant # \_\_\_\_\_ Group # \_\_\_\_\_**