

Accelerated Approval Focus Groups Participant Screener

Notes to the facility:

- Do not call people who have participated in a focus group or other interview-based projects in the last three months.
- When calling potential participants, recruiters should use general interactions throughout all calls to make judgements about each person's ability and willingness to participate in a focus group discussion. We are looking to recruit a diverse group of participants, not just individuals who are especially talkative and articulate. Although everyone will be expected to participate in the discussion, there is no expectation that everyone will answer every question. All participants will need to be comfortable conversing in English.

Recruiting goals:

- All participants must be able to read, understand, and speak English.
- Sufficient recruits will be invited to achieve a target of nine participants per group.
- Two groups will be recruited at each facility—a low literacy group and an average/high literacy group. Instructions are provided for how to categorize participants in each group.

Study protocol:

- Each group will last approximately one hour.
- Groups will be audio recorded and live-streamed.
- Informed consent sheets will be distributed at sign-in, and a verbal consent will be obtained before the start of the discussion.
- The identity of the participants will remain confidential.
- Groups may be observed by staff from the U.S. Food and Drug Administration.
- Participants do not have to answer any questions that they do not want to but are encouraged to participate.

Group Composition and Location:

GROUP #	LOCATION	Group	Location
1	Northeast/Mid-Atlantic	Average/High literacy	Arlington, VA; Baltimore, MD
2		Low literacy	
3	Mid-West	Average/High literacy	Oklahoma City, OK
4		Low literacy	
5	Southwest	Average/High literacy	Albuquerque, NM
6		Low literacy	

7	South	Average/High literacy	Little Rock, AK
8		Low literacy	

RECRUITMENT SCRIPT:

TELEPHONE

Hello Mr./Ms. _____, my name is _____ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration in your area. We are recruiting for an upcoming focus group during which participants will be asked to share their thoughts about and experiences with prescription drugs. Participants in this study will receive \$75. Let me assure you that this is a legitimate research study. I am not trying to sell anything.

WEB

We are looking for participants to take part in a research study in your area sponsored by the U.S. Food and Drug Administration. Participants will be asked to share their thoughts and experiences with prescription drugs during a 60-minute focus group. Participants in this study will receive \$75.

[Note: Language below is for telephone recruitment. Language will be adjusted for online screener tools.]

1. Are you interested in participating?
 - YES → CONTINUE
 - NO → ELIMINATE

2. We would like to ask you a few questions just to see if you qualify for this study. These questions will only take a few minutes of your time. Do you have time now to answer these questions?
 - YES → CONTINUE
 - NO → ELIMINATE

3. I am going to read some age categories. Could you please tell me in which category your age falls? [RECRUIT A MIX FOR EACH AGE CATEGORY WITHIN EACH GROUP AND ACROSS THE STUDY. SOFT QUOTA IS OK BUT ENSURE NO ONE AGE GROUP IS OVERREPRESENTED]
 - UNDER 18 YEARS OLD → ELIMINATE [ASK TO SPEAK WITH SOMEONE AT LEAST 18 YEARS OLD]
 - 18-30 → CONTINUE
 - 31-44 → CONTINUE
 - 45-64 → CONTINUE
 - 65+ → CONTINUE

4. DETERMINE GENDER [ENSURE EVEN MIX]

- MALE → CONTINUE
 - FEMALE → CONTINUE
5. The focus group will be conducted in English. Are you comfortable reading and speaking English?
- YES → CONTINUE
 - NO → ELIMINATE
6. Do you or someone from your immediate family work for any of the following:
- A market research firm → ELIMINATE
 - The U.S. Food and Drug Administration → ELIMINATE
 - A pharmaceutical company → ELIMINATE
7. Are you a medical professional?
- YES → ELIMINATE
 - NO → CONTINUE
8. During the past two years, have you had a medical condition for which you visited a doctor or hospital?
- YES → CONTINUE
 - NO → ELIMINATE
9. Have you (or someone in your close family) ever suffered from a serious medical condition?
- YES, I HAVE → CONTINUE
 - YES, SOMEONE IN MY CLOSE FAMILY → CONTINUE
 - NO → CONTINUE
10. How confident are you filling out medical forms by yourself?
- A. Extremely → CONTINUE
 - B. Quite a bit → CONTINUE
 - C. Somewhat → CONTINUE
 - D. A little bit → CONTINUE
 - E. Not at all → CONTINUE
11. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?
- A. Always → CONTINUE
 - B. Often → CONTINUE
 - C. Sometimes → CONTINUE
 - D. Rarely → CONTINUE
 - E. Never → CONTINUE
12. What is the highest level of education that you have completed? [READ ALL ANSWER OPTIONS. SEE BELOW FOR RECRUITMENT DIRECTIONS]
- A. Less than high school → CONTINUE

- B. High school graduate or GED → CONTINUE
- C. Technical/vocational school → CONTINUE
- D. Some community college → CONTINUE
(toward an associate degree or other community college degree)
- E. Community college degree (for example, an associate degree) → CONTINUE
- F. Some college (toward a bachelor's degree) → CONTINUE
- G. College degree (a bachelor's degree) → CONTINUE
- H. Advanced degree (postgraduate degree) → CONTINUE

[RECRUIT INTO LOW LITERACY GROUP BASED ON FOLLOWING CRITERIA;
OTHERWISE RECRUIT TO AVERAGE/HIGH LITERACY GROUP]

Q10	Q11	Q12	Group
C/D/E	Any	Any	Low literacy
Any	A/B/C	Any	Low literacy
Any	Any	A/B/C	Low literacy

13. Are you of Hispanic or Latino origin? [RECRUIT A DIVERSE GROUP REFLECTIVE OF THE AREA]

- YES → CONTINUE
- NO → CONTINUE

14. What is your race? I am going to read several categories of race. You may choose one or more categories. Are you...? [RECRUIT A DIVERSE GROUP REFLECTIVE OF THE AREA.]

- White
- Black or African American
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaska Native
- Other

15. I am going to read some income categories. Could you classify your annual household income to one of these categories? [RECRUIT A MIX PER GROUP]

- Less than \$25,000 per year
- \$25,000 to less than \$50,000 per year
- \$50,000 to less than \$75,000 per year
- \$75,000 and over per year

TERMINATION LANGUAGE: I'm sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible. These reasons

were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

FINALIZING SCREENER QUESTIONS FOR ALL GROUPS

Thank you for answering these questions. We would like to invite you to participate in a focus group with about eight other participants to discuss issues relating to prescription drugs. The discussion will last approximately an hour. The discussion will be audio recorded and observed by researchers. Your participation and everything you say during the discussion will remain confidential and your personal identifying information will not be included in any reports. At the conclusion of the focus group, you will receive \$75 as a token of our appreciation for your participation. Are you interested in participating in this focus group?

- Yes [CONTINUE]
- No [THANK THE PERSON FOR HIS/HER TIME]

I'm glad that you will be able to join us! The focus group will take place on (DAY), (DATE), at [6:00 or 8:00 p.m.] at [SITE LOCATION].

Will you be available to participate at this time?

- Yes [CONTINUE]
- No [THANK THE PERSON FOR HIS/HER TIME]

I would like to send you a confirmation of the time and date and directions to the facility. In order to do so, could you please give me either your email address or a home address to send the letter?

Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if, for some reason, you are unable to attend. Please call [RECRUITER] at [TELEPHONE NUMBER] if this should happen. We look forward to seeing you on [DATE] at [TIME]. If you use reading glasses, please bring them with you to the focus group.