

**Focus Groups & In Depth Interviews to Understand Perceptions Of/Attitudes
Toward FDA CDER Drug Safety Communications:
Participant Screener (FDA Personnel, Healthcare Professionals, Non
Healthcare Professionals)**

Recruiting Goals

- *FDA Personnel:* 4 focus groups and no more than 20 interviews will be conducted in the Washington DC Metropolitan area. Focus groups and interviews will be held in FDA facilities.

Healthcare Professionals & Non-Healthcare Professionals: 4 focus groups for healthcare professionals and 4 focus groups for non-healthcare professionals will be held in the Washington DC Metropolitan area.

See table below for specifications at each location.

- All participants must be able to read, understand, and speak English.
- *Healthcare Professionals and Non-Healthcare Professionals:* 12 recruits per group in order to get a minimum of 9 to participate.

No more than 20 FDA Personnel will be recruited for this effort.

- Healthcare professionals will receive a \$200 stipend; Non-Healthcare Professionals will receive a \$90 stipend; federal employees are not eligible to receive a stipend.
- *FDA Personnel:* Focus groups/interviews will last approximately 90 minutes and will be audio taped.

Healthcare Professionals and Non-Healthcare Professionals: Focus groups will last approximately 120 minutes and will be audio and video taped.

- Participants do not have to answer any questions that they do not want to, but are encouraged to participate in the groups. The identity of the participants will remain private to the extent permitted by law.
- Food and Drug Administration staff and other research team members will observe the groups.

Schedule

Group #	Group Composition	Date & Time	Location
Group I	FDA Personnel	TBD	Washington, DC
Group II	FDA Personnel	TBD	Washington, DC
Group III	FDA Personnel	TBD	Washington, DC
Group IV	FDA Personnel	TBD	Washington, DC
Group V	Healthcare Professionals	TBD	Washington, DC, area
Group VI	Healthcare Professionals	TBD	Washington, DC, area
Group VII	Healthcare Professionals	TBD	Washington, DC, area
Group VIII	Healthcare Professionals	TBD	Washington, DC, area
Group IX	Non-healthcare professionals	TBD	Washington, DC, area
Group X	Non-healthcare professionals	TBD	Washington, DC, area
Group XI	Non-healthcare professionals	TBD	Washington, DC, area
Group XII	Non-healthcare professionals	TBD	Washington, DC, area

Participant Screener for Adult Focus Groups

Hello, my name is _____ and I'm calling about a market research study in your area. We are recruiting for an upcoming focus group in which participants will be asked to share their thoughts and feelings about medicines.

Would you mind answering a few questions? All of the information you provide will remain private to the extent permitted by law.

Screening Questions

Q1. Are you a healthcare professional?

- Yes → continue, Go to Q2
- No → Go to Q3

Q2. In what capacity are you in the healthcare field?

- Yes → assign to **healthcare professional** group, Go to Q3
- No → continue, Go to Q3

Q3. Are you familiar with FDA's Drug Safety Communications (DSCs)?

- Yes → assign to **healthcare professional** group, Go to Q4
- No → continue, Go to Q4

Q4. Do you actively engage with others online about drug safety, drug information, FDA or other medical issues (e.g., blogger, tweeter, active Facebook user)?

- Yes → continue, Go to Q4a
- No → eliminate

Q4a. Do you communicate frequently (at least one time per week) online outside of regular email about the topics mentioned above (e.g., blogging, tweeting, etc.)?

- Yes → (assign to non healthcare professional group if applicable)
- No →

Q5. Do you or someone from your immediate family work or have worked or are retired from any of the following:

- Market Research Firm → eliminate [thank respondent politely]
- The Food and Drug Administration → eliminate [thank respondent politely]
- The National Institutes of Health → eliminate [thank respondent politely]
- Pharmaceutical Company → eliminate [thank respondent politely]
- Physician office, hospital, clinic, or pharmacy → eliminate [thank respondent politely]
- The Department of Health and Human Services → eliminate [thank respondent politely]
- A State Health Department → eliminate [thank respondent politely]

Q6. Have you participated in a focus group within the past six months?

[Interviewer: participation in telephone surveys is allowable]

- Yes → eliminate [thank respondent politely]
- No → continue

Demographic Questions

Q7. Gender

- Male
- Female

Q8. How old are you? (if under 21 or over 61, eliminate and thank politely)

- Under 21
- 21 – 30 years old (include)
- 31 – 40 years old (include)
- 41 – 50 years old (include)
- 51 – 60 years old (include)
- 61 or older

Q9. What is the highest level of education that you have completed?

- Less than high school
- High school graduate or GED
- Technical/vocational school
- Some college credit but no degree
- Associate's degree (AA, AS)
- Bachelor's degree (BA, AB, BS)

- Advanced degree (MA, MS, MEd, MEng, MBA, MSW, PhD, MD, JD, DVM, EdD)

Q10. Are you of Hispanic, Latino, or Spanish origin?

- Yes
- No

Q11. What is your race? Please select one or more.

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

We would like to invite you to participate in a focus group to discuss issues relating to Drug Safety Communications with 8 to 10 other participants. The focus group will take place on (Day), (Date), at [6:00 or 8:00 p.m.] at [site location]. The discussion will last approximately an hour and twenty minutes and will include both men and women. The group will be audio and video taped and observed by staff from the federal Food and Drug Administration. However, your participation and everything you say during the discussion will be kept private and confidential to the extent permitted by law. The FDA will not have your full names and will keep all tapes locked up until they are destroyed.

Healthcare professionals will receive **\$200** cash for your time.

Non-Healthcare Professionals will receive **\$90** cash for your time.

Additionally light refreshments such as [insert type of food served] before the group discussion will start. 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 letter and directions to the focus group facility. Can you please tell me your mailing address (or fax number) and a phone number where you can be reached:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Email: _____

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.