



Attachment 5A:
**NIH Clinical Trial Awareness Campaign Planning
Message Testing Research
Focus Groups with Public, Patients, and Caregivers**

Moderator's Guide

Public reporting burden for this collection of information is estimated to average 120 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-05). Do not return the completed form to this address.

I. WELCOME (5 minutes)

Welcome everyone. My name is [MODERATOR NAME], and I work for AED, a nonprofit organization, working on a research project for the National Institutes of Health, or NIH. We are talking to people to hear about what people know and think about clinical studies. Thank you for coming to this discussion.

Before we begin, I'd like to explain a few things about this room and how the discussion will work.

1. We are not selling or promoting any product or service to you.
2. There are **no right or wrong answers** -- We want to know your honest opinions.
3. I do not work for the people who are sponsoring this research, and I was not personally involved in the development of any of the ideas and items that I am going to share with you today. If you have something negative to say, it is all right.
4. Don't feel like you need to answer every question. But if I haven't heard from you in awhile I may call on you occasionally.
5. There are microphones in this room that we are using to **audiotape** our discussion. I have to write a report afterwards, and the tapes it will help me remember what you've said here today.

6. Because we are taping, it is important that you try to **speak one at a time**. I may occasionally interrupt you when two or more people are talking at once to be sure everyone gets a chance to talk and that responses are accurately recorded.
7. Behind me is a **one-way mirror**. Some of the people working on this project are watching this discussion so that they can hear your opinions directly from you. However, your identity and anything you personally say here will be kept secure. When I write my report, I will not refer to anyone by name.
8. The group will last for **1 hour and 30 minutes**. I do not to keep you here any longer, so I may occasionally interrupt the discussion to move us along.
9. Please turn off your **beepers & cell phones**. Should you need to go to the restroom during the discussion, please feel free to leave, but we'd appreciate it if you would go one at a time.
10. Your feedback will be kept secure to the extent permitted by law. We will write a summary of what we've heard for the National Institutes of Health. We will not include anyone's names or other identifying information.

Do you have any questions before we get started?

II. INTRODUCTIONS (5 minutes)

Let's go around the table and introduce ourselves:

- Please tell us your first name, and
- Share with us what family health problems that worry you at times.

III. GENERAL DISCUSSION OF CLINICAL TRIALS (25 minutes)

One of the purposes of the National Institutes of Health is to fund and support medical research. One way of doing research is with clinical studies, often called "clinical trials".

1. Tell me what you've heard about clinical studies. How would you describe them?
[PROBE: what are they for? What happens in a clinical study?]
2. Before we get more specific, let's brainstorm for a few moments. [Moderator uses flipchart to generate a free association list.]
When you hear the words "Clinical trials", what words or thoughts come to mind?
[Participants will generate list of words and explain them.]
 - What positive things do you associate with "clinical trials"? Why? (could be already mentioned, or additional ones)
 - What negative things do you associate with "clinical trials"? Why? (could be already mentioned, or additional ones)

3. What types of people volunteer for clinical studies? Why do you think they might join a study?
4. What might be some reasons that people decide not to join clinical studies?

Personal experiences

5. Have any of you thought about volunteering for a clinical study? Why or why not?
6. Has a doctor or other health professional ever mentioned a study to you? What did he/she say?
7. Have any of you ever looked for information about clinical studies, for yourself or for someone else? What were you looking for? Where did you look? If not, where might you look if you wanted to get more information about clinical studies?

IV. FEEDBACK ON MESSAGE CONCEPTS (45 minutes)

The National Institutes of Health would like Americans to know more about clinical studies and their importance in finding treatments for disease.

Next, we will look at some messages they developed to get the word out about clinical studies. I would like to hear your feedback about each of these. You might see these as text in an ad on TV or in a magazine. After I show you each one, I will ask you a few questions to get your reactions.

[Show boards according to rotation schedule; ask questions for each one.]

1. If you had to give this message a grade, like in school, where “A” is the best and “F” is a failing grade, what grade would you give this message as a choice for an ad campaign? Please jot it down on the paper in front of you.

How many of you gave this message an “A”? [Moderator asks for a show of hands. Moderator continues to ask for other grades and writes them on a flipchart.]

2. What is the main idea of this message? [**Probe:** What are they trying to say in this message?]
3. Does seeing this idea make you interested in seeing more of information? [**Probe:** Does it get your attention? Are you drawn to it in any way?]
4. How believable is the message? What additional information would you need in order to more strongly believe this message?
5. Is there anything confusing, unclear, or hard to understand? Are there any words that are unusual or unfamiliar? What other words can be used in their place?

6. Does it seem like this message is talking to you, and people like you? Or someone else? What in the message suggested it was talking to you and people like you or someone else?
7. Is this idea relevant to you or your family? [Probe: Why/why not?]
8. What, if anything, is it asking you to do?
9. Do you find anything that raises concerns?
10. What kinds of information would you like to see if it becomes a longer ad?
11. What other comments do you have about this message?

Summary discussion

[Moderator shows all messages and grades together on flipchart or prepared board.]

Let's look at all these messages together, now that we've seen them all. Do you think these grades still reflect what you think about each of them?

Which ones do you feel are more relevant to you, personally? Which ones are rising to the top as the most interesting and appealing to you?

V. CHANNELS (10 minutes)

OK, let's go back to when we introduced ourselves. Most/All of us have health issues in our families that concern us. Thinking about this, let's talk a bit about where we go to get information about health and medical issues.

1. Where do you get your information about health and medical issues [Probe for sources such as media, family, friends, church]
2. What are some of the ways you have gotten information about treatment options or choices or future treatments that might become available? [Probe: role of physician, word-of-mouth, disease associations, media.]
3. When it comes to clinical studies and medical research, are there any organizations that you would really trust as a reliable source of information? [Probe: Medical groups, disease groups] What makes them a trusted source?
4. What are some places where you might expect to get more information about clinical studies, like messages like the ones we just saw? Are there some places in particular that you would be most likely to pay attention to this information? [Probe: social media; libraries; trustworthiness of various sources mentioned]

VI. CONCLUSION (5 minutes)

1. Before we conclude, is there anything else you would like to share, or do you have any questions for me?
2. Thank you for sharing your opinions and feedback on the Web site concepts we have shared with you today. NIH will be using your input to develop and refine these messages.

THANK YOU!



**Attachment 5B:
TESTING OF MESSAGES FOR AN NIH CLINICAL TRIAL
PUBLIC AWARENESS CAMPAIGN - FOCUS GROUP
RECRUITMENT SCREENER**

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-16). Do not return the completed form to this address.

Summary Table

Group	Location	Date/Time	Audience
#1	Market 1	TBD	General Public
#2	Market 2	TBD	General Public
#3	Market 1	TBD	Persons who have a family history of a serious illness that has a limited standard of care
#4	Market 3	TBD	Persons who have a family history of a serious illness that has a limited standard of care
#5	Market 1	TBD	Caregivers or family members of persons who are with long term chronic/terminal illness
#6	Market 2	TBD	Caregivers or family members of persons who are with long term chronic/terminal illness
#7	Market 1	TBD	Persons with long term chronic/terminal illness
#8	Market 2	TBD	Persons with long term chronic/terminal illness
#9	Market 3	TBD	Persons with long term chronic/terminal illness
#10	Market 1	TBD	Cancer survivors who have recently completed treatment
#11	Market 2	TBD	Cancer survivors who have recently completed treatment
#12	Market 3	TBD	Cancer survivors who have recently completed treatment

Recruitment:

For each focus group recruit 10 for 8 participants to show

[Request to speak with an adult in the household.]

Hello, I'm _____. I work for _____, an independent research firm. We are doing a study for the National Institutes of Health or NIH to find out what people know about health research, including clinical trials; to get their input regarding messages about clinical trials and research on treatments for chronic and life-threatening diseases; and to explore how and where audiences prefer to get this type of information. We are looking for people to take part in discussion groups about these topics. Input and ideas from these discussions will help inform NIH about how to provide information on clinical research to the public. We are not selling any product or service. Everyone who is eligible and participates will be given an incentive **\$100** as a thank you for your time.

The discussion groups will be held on **[Dates]** at **[Place]** and will last about two hours. I would like to ask you some questions to see if there is a discussion group that you could join. These questions will only take a few moments to answer. Do you have time now to answer a few questions?

To make sure we include a variety of people in our discussions, I'd like to ask you a few questions...

1. Are you or is anyone in your household . . .

A computer programmer, professional web designer, or usability tester? _____

Employed in advertising, marketing, market research, public relations,
public health or health promotion? _____

An employee or volunteer in the medical field or healthcare industry? _____

(In Market 1) An employee of the Federal government? _____

(In Markets 2 & 3) An employee of the US Dept of Health and Human Services (DHHS) _____

Terminate >> If any YES

2. Do you work for the American Cancer Society, the National Cancer Institute or a similar organization that focuses on cancer, or does your work involve people with cancer or their families?

Terminate>> Yes _____
No _____

3. Have you ever taken part in a clinical trial?

No _____
Terminate>> Yes _____

4. I would appreciate it if you would answer the following questions about your health.

[Groups 10-12] >>Are you a cancer survivor?

[Go to Groups 7-9 question] No _____
Yes _____

(If Yes) Did you complete your cancer treatments within the past 36 months/3 years?

[Go to Groups 7 - 9 question] No _____
[Go to Group 10 – 12 screener → if not fully recruited] Yes _____

[Groups 7-9] >>Do you have a long term chronic/terminal illness like Parkinson's, MS, diabetes, lupus, ESRD, COPD, congestive heart failure?

[Go to Groups 3 & 4 question] No _____
[Go to Group 7 – 9 screener → if not fully recruited] Yes _____

[Groups 3 & 4] >>Do you have a family medical history that includes a serious illness with a limited standard of care? That is, does a blood relative either have or did one have a serious illness where there is not a good way to treat or manage it? Illnesses like these include Alzheimer or Lou Gehrig's.

[Go to Groups 5 & 6 question] No _____
[Go to Group 3 & 4 screener → if not fully recruited] Yes _____

[Group 5 & 6] >>Are you the family member of or are you or have you ever been a caregiver for someone who has a long term chronic or terminal illness like Parkinson's, MS, diabetes, lupus, ESRD, COPD, congestive heart failure

[Go to Groups 1 & 2 question] No _____
[Go to Group 5 & 6 screener → if not fully recruited] Yes _____

[Groups 1 & 2] >>Is it true I would like to confirm that none of the previously mentioned health scenarios fit you. Is this correct?

[FIND OUT WHICH OF THE ABOVE HEALTH SCENARIOS APPLYS] No _____
[Go to Groups 1 & 2 screener → if not fully recruited] Yes _____

GROUPS 1 AND 2

1. **[FOR GROUPS 1 & 2]** Have you ever been a caretaker for an adult who has had an extremely serious, chronic or terminal illness?

No _____

Consider for Groups 5 & 6 but Terminate for Groups 1 & 2>> Yes _____

2. What is your age?
AGE]

|_|_|_| [RECORD

[Recruit a mix]

Terminate>> Under 40 _____

40-50 _____

51-59 _____

Terminate>> Over 60 _____

Terminate>> Refuse _____

3. What is the highest level of education you have completed? **[Recruit a mix]**

Less than high school _____

High school diploma/GED _____

Some college _____

College degree _____

Master's level graduate degree _____

(No more than 1 per group) Doctoral level graduate degree (MD, JD, PhD) _____

Terminate>> Refuse _____

4. Do you consider yourself Hispanic or Latino?

Yes _____

No _____

Terminate>> Refuse _____

5. Which of the following best describes your race? **[Recruit a Mix]**

American Indian or Alaska Native _____

Asian _____

Black or African American _____

Native Hawaiian or Other Pacific Islander _____

White _____

Terminate>> Refuse _____

(Recruit at least 4 participants who are non-white or Hispanic for each group.)

GO TO "COMMON QUESTIONS" (PAGE 10)

GROUPS 3 & 4 - Persons who have a family history of a serious illness that has a limited standard of care

1. We are seeking a variety of perspectives. If I may ask, what serious illness that currently has limited means of treating it do you have a family history of?

[Record type(s) of illness] _____

2. Who in your family has or had this disease?

[Record relationship] _____

3. What is your age?
AGE]

|__| |__| [RECORD

[Recruit a mix]

Terminate>> Under 30 _____
30-39 _____
40-49 _____
50-59 _____
60-65 _____
Terminate>> Over 65 _____
Terminate>> Refuse _____

4. Do you consider yourself Hispanic or Latino?

Yes _____
No _____

Terminate>>Refuse _____

5. Which of the following best describes your race? [Recruit a Mix]

American Indian or Alaska Native _____
Asian _____
Black or African American _____
Native Hawaiian or Other Pacific Islander _____
Caucasian/White _____
Terminate>> Refuse _____

(Recruit at least 4 participants who are non-white or Hispanic for each group.)

GO TO "COMMON QUESTIONS" (PAGE 10)

GROUPS 7, 8, & 9 - Person who has a long term chronic/terminal illness like Parkinson's, MS, diabetes, lupus, ESRD, COPD, congestive heart failure

1. We are seeking a variety of perspectives. If I may ask, what long term chronic or terminal illness are you suffering from?

[Record disease] _____

2. When, approximately, were you initially diagnosed?....

[Record when] _____

3. Do you consider yourself Hispanic or Latino?

Yes _____

No _____

Terminate>> Refuse _____

4. Which of the following best describes your race? [Group 7 should be ALL African American – can be Hispanic as well. For Groups 8 & 9 - Recruit a Mix]

American Indian or Alaska Native _____

Asian _____

Black or African American _____

Native Hawaiian or Other Pacific Islander _____

Caucasian/White _____

Terminate>> Refuse _____

5. What is your age?
AGE]

____|____| [RECORD

[Recruit a mix]

Terminate>> Under 30 _____

30-39 _____

40-49 _____

50-59 _____

60-65 _____

Terminate>> Over 65 _____

Terminate>> Refuse _____

GO TO “COMMON QUESTIONS” (PAGE 10)

GROUPS 10, 11, & 12 – Cancer survivors who have recently completed treatment

1. We are seeking a variety of perspectives. If I may ask, what type of cancer were you diagnosed with?

[Record type(s) of cancer] _____

2. Can you tell me when your last treatment was....

[Record when] _____

Terminate>> More than one year ago _____
1 year ago or less _____

3. Do you consider yourself Hispanic or Latino?

Yes _____

No _____

Terminate>> Refuse _____

4. Which of the following best describes your race? [Group 10 should be ALL African American – can be Hispanic as well. For Groups 11 & 12 - Recruit a Mix]

American Indian or Alaska Native _____

Asian _____

Black or African American _____

Native Hawaiian or Other Pacific Islander _____

Caucasian/White _____

Terminate>> Refuse _____

5. What is your age?
AGE]

____|____| [RECORD

[Recruit a mix]

Terminate>> Under 30 _____

30-39 _____

40-49 _____

50-59 _____

60-65 _____

Terminate>> Over 65 _____

Terminate>> Refuse _____

GO TO “COMMON QUESTIONS” (PAGE 10)

GROUPS 5 & 6 – Caregiver/family member of person who has a long term chronic/terminal illness

1. What is your relationship to the person who is ill?

Spouse/Partner _____
Sibling _____
Parent/Guardian _____
Aunt/Uncle/Grandparent _____
Other family member _____
Friend _____
Other (please specify _____) _____
Terminate>> Refuse _____

2. We are seeking a variety of perspectives. If I may ask, what long term chronic or terminal illness is this individual suffering from?

[Record disease] _____

3. When, approximately, was the illness diagnosed?....

[Record when] _____

4. Have you ever taken part in a clinical trial?

No _____
Terminate>> Yes _____

5. How much are you or were you involved in finding information on treatment options for your family member/the person for whom you are a caregiver? Would you say that you are or were...

Terminate >> Not at all involved _____
Terminate >> Slightly involved _____
Somewhat Involved _____
Very much involved _____

6. Do you consider yourself Hispanic or Latino?

Yes _____
No _____
Terminate>>Refuse _____

7. Which of the following best describes your race? **[Recruit a Mix]**

- American Indian or Alaska Native _____
- Asian _____
- Black or African American _____
- Native Hawaiian or Other Pacific Islander _____
- Caucasian/White _____
- Terminate>>** Refuse _____

8. What is your age?
AGE]

|__|__| **[RECORD**

[Recruit a mix]

- Terminate>>** Under 30 _____
- 30-39 _____
- 40-49 _____
- 50-59 _____
- 60-65 _____
- Terminate>>** Over 65 _____
- Terminate>>** Refuse _____

GO TO “COMMON QUESTIONS” (PAGE 10)

COMMON QUESTIONS

1. What is the highest level of education you have completed? **[Recruit a mix]**

- Less than high school _____
High school diploma/GED _____
Some college _____
College degree _____
Master's level graduate degree _____
(No more than 1 per group) Doctoral level graduate degree (MD, JD, PhD) _____
Terminate>> Refuse _____

2. Can you tell me about a place you get reliable health information?

[Record name] _____

[This question is intended to establish whether the respondent is reasonably articulate and audible, fluent in English, and willing to converse. If respondent has a strong accent, difficulty speaking English, serious speech impediment or has trouble communicating (e.g., "shuts down"), thank and terminate.]

3. **[DO NOT ASK. RECORD WHETHER RESPONDENT IS MALE OR FEMALE. RECRUIT ABOUT HALF EACH.]**

Female _____
Male _____

4. How comfortable are you reading and speaking English in a group? **[Read options]**

Very comfortable _____
Terminate>> Somewhat comfortable _____
Terminate>> Not at all comfortable _____

5. Have you participated in any research projects where you were asked to participate in a group discussion with 6-10 people and an interviewer who led the discussion?

Continue>> Yes _____
Go to Invitation>> No _____

5a. How many of these types of projects have you participated in, in the last year?

|__|__| **[RECORD #]**

Terminate>> Three or more _____
0, 1, or 2 _____

[IF ELIGIBLE, GO TO "INVITATION" TO SIGN THEM UP FOR FOCUS GROUP]

****TERMINATE LANGUAGE:** Thank you very much for your time. We have recruited all of the persons like you that we need to talk to, so we won't be able to include you in our study. Thank you for your time and interest. Have a good day/evening.

INVITATION

Thank you for answering my questions. I would like to tell you a little more about the discussion group. The group will meet on **[Date]** at **[Time]** at our facility in **[Location]**. **[Give address]**. You will join up to 9 other people and a moderator. The group will meet for about two hours. As a thank you for your participation in the discussion you will receive **\$100**.

So that we can start and end on time, please come about 15 minutes early to pick up your nametag and have some snacks. Please be sure to contact us as soon as possible if something comes up and you can't come. **(Give phone number)**.

If you wear reading glasses or use a hearing aid, please remember to bring them with you to the discussion.

Before we hang up, let me get the correct spelling of your name, and your address and phone numbers so we can send you a letter with directions and give you a reminder call the day of the group.

NAME _____

HOME PHONE _____

ADDRESS _____

WORK PHONE _____ CELL PHONE _____ E-MAIL _____

Thanks again for your time and we'll see you at the group!