

Audience Research on Self-Management Education Phase III

Attachment 5 to the HMTS Expedited Review Form

Contents

Attachment 5a: Informed Consent Form.....1
Attachment 5b: Informed Consent Form: Participant Copy.....2

Attachment 5a: Informed Consent Form

Audience Research on Self-Management Education Phase III

| | |
|--|--|
| Identification of Project | CDC Discussion Groups |
| Purpose | The Centers for Disease Control and Prevention (CDC) is the sponsor of this research study. FHI 360 is helping with this study. The purpose of this research study is to gather feedback regarding materials related to programs designed to help people manage their ongoing health problems. It will help inform how CDC and its partners can better communicate health-related information to audiences with ongoing health conditions. |
| Procedures | We have asked you to join a focus group (a group discussion). The discussion will take place in a professional research facility. The room that the discussion will take place will have a one-way mirror. Behind the one-way mirror is an observation room where people who work on the project may listen to discussion without being seen, so that they will not be a distraction to the group. During the discussion, you will be asked about your thoughts and opinions regarding several materials related to health and to the work of CDC and its partners. You will also be asked to introduce yourself using your first name or whatever you would like to be called and state which ongoing health condition that you are experiencing. The group will have up to seven other people. All participants live in communities near the research facility and have at least one ongoing health problem. The group will last no more than 90 minutes. A trained person will lead the discussion group. |
| Information Security | We will make audio recordings of the group. In addition, some people who work on the project may listen to the recordings and may also listen during the discussion group from the observation room or via the telephone. They will write a report based on their notes and the recordings. However, no one outside of this project will listen to the recordings. We will keep what you say secure to the extent permitted by law. Please note, although we are asking group members not to discuss what was said during this discussion with anyone outside the group, we cannot guarantee confidentiality. We will NOT put your name in the report or on the recordings. We will keep the recordings in a locked cabinet. The recordings will be destroyed by 2017. |
| Risks | The risks of your participation are expected to be minimal. This means that the risks are not expected to be greater than the risks persons may normally find in their daily life. |
| Benefits, Freedom to Withdraw, & Ability to Ask Questions | This project is not designed to help you personally. It is intended to help CDC understand how to best communicate certain health-related information to different audiences. You do not have to answer questions that you do not want to answer. You may stop at any time. You will receive \$50 to show appreciation for your completed participation. |
| Contact Information | If you have any questions, please contact FHI 360's Office of International Research Ethics (phone number: 1-919-405-1445, e-mail: PHSC@fhi360.org). |

My signature confirms that I have read the information on this page. I am at least 18 years of age and understand my rights as a participant. I agree to take part in this discussion group. I agree to have audio recordings made of the discussion. I realize that only the people working on this project will listen to the recordings and that they may also listen during the discussion groups. I understand that my name will NOT be used in the report or any other products. No other information that could identify me will be used either.

Signature: _____

Name (Please print): _____

Date: _____

Attachment 5b: Informed Consent Form: Participant Copy

Audience Research on Self-Management Education Phase III

| | |
|--|--|
| Identification of Project | CDC Discussion Groups |
| Purpose | The Centers for Disease Control and Prevention (CDC) is the sponsor of this research study. FHI 360 is helping with this study. The purpose of this research study is to gather feedback regarding materials related to programs designed to help people manage their ongoing health problems. It will help inform how CDC and its partners can better communicate health-related information to audiences with ongoing health conditions. |
| Procedures | We have asked you to join a focus group (a group discussion). The discussion will take place in a professional research facility. The room that the discussion will take place will have a one-way mirror. Behind the one-way mirror is an observation room where people who work on the project may listen to discussion without being seen, so that they will not be a distraction to the group. During the discussion, you will be asked about your thoughts and opinions regarding several materials related to health and to the work of CDC and its partners. You will also be asked to introduce yourself using your first name or whatever you would like to be called and state which ongoing health condition that you are experiencing. The group will have up to seven other people. All participants live in communities near the research facility and have at least one ongoing health problem. The group will last no more than 90 minutes. A trained person will lead the discussion group. |
| Information Security | We will make audio recordings of the group. In addition, some people who work on the project may listen to the recordings and may also listen during the discussion group from the observation room or via the telephone. They will write a report based on their notes and the recordings. However, no one outside of this project will listen to the recordings. We will keep what you say secure to the extent permitted by law. Please note, although we are asking group members not to discuss what was said during this discussion with anyone outside the group, we cannot guarantee confidentiality. We will NOT put your name in the report or on the recordings. We will keep the recordings in a locked cabinet. The recordings will be destroyed by 2017. |
| Risks | The risks of your participation are expected to be minimal. This means that the risks are not expected to be greater than the risks persons may normally find in their daily life. |
| Benefits, Freedom to Withdraw, & Ability to Ask Questions | This project is not designed to help you personally. It is intended to help CDC understand how to best communicate certain health-related information to different audiences. You do not have to answer questions that you do not want to answer. You may stop at any time. You will receive \$50 to show appreciation for your completed participation. |
| Contact Information | If you have any questions, please contact FHI 360's Office of International Research Ethics (phone number: 1-919-405-1445, e-mail: PHSC@fhi360.org). |