Medical Countermeasures Message Testing

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Appendix C. Participant Information Sheet

U. S. Department of Health and Human Services

Food and Drug Administration [FDA] Study

Information for Participants

Purpose of this group discussion

You are being asked to participate in a research study being conducted by the Food and Drug Administration (FDA), with the assistance of The Oak Ridge Associated Universities (ORAU). In the discussion, you will be asked your opinions and practices regarding some information about messages that might be provided to the public during an emergency. Your answers can help efforts to provide accurate, helpful information to the public during a public health emergency. The discussion will be recorded (audio only) to be sure we get all of your comments.

Procedures:

We have asked you to join a group discussion called a focus group .The discussion will take place in a professional research facility. During the discussion, you will be asked your opinions and practices regarding some information about messages that might be provided to the public during an emergency. The group will consist of approximately eight people. A trained person will lead the discussion group. The total time involved in the interview, including instructions, will be no more than 90 minutes.

Please remember that:

You choose to participate.
You are not required to answer the questions.
This session should last about 90 minutes.
The session will not be video recorded.
You will receive $XX as a token of appreciation for participating in the discussion.
You are free to leave at any time without penalty, and you will still receive the $XX as a token of appreciation.
Researchers will be observing the research project either in-person or remotely through a real-time online video streaming mechanism.

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

You may be better informed about a public health issue.
You may have a sense of satisfaction from contributing to a research study.
Your comments may help improve the information FDA provides to the public about the drug treatments used in public health emergencies.

We will keep the information you give us private to the extent allowed by law. Your name will not be used in the final report. No statement you make will be linked to you by name. Only members of the research staff

will be allowed to look at the records, which will not connect your name to any comments you have made. When we present this study or publish its results, your name or other facts that point to you will not be included.

Persons to Contact

If you have questions about this session, or taking part in it, you may call: Karen Carera at 404-291-2236 at ORAU.

If you need more information about your rights as a study participant, you may contact:
Oak Ridge Site-Wide Institutional Review Board, ORAU, Oak Ridge, TN 865- 576-1725 or ORSIRB@orau.org