Attachment E

OMB Control No: 0910-0497
Expiration Date: 12/31/2026

Focus Groups Examining Consumer Reporting of Adverse Events

Purpose:

- The U.S. Food and Drug Administration (FDA) is conducting this focus group study to learn about certain experiences consumers may have had with prescription or over-the-counter drugs ("human drug products").

What is involved:

- Your participation is voluntary. You do not have to participate if you do not want to. You may also choose not to answer a question for any reason.
- If you choose to participate, we will ask you some questions about certain experiences you may have had taking a human drug product. Up to five other people will be part of the discussion.
- The focus group discussion will take approximately 60 minutes.
- You will be asked to log in 15 minutes before the scheduled start time to ensure your audio and video are working.

Confidentiality:

- Everything you say in the focus group will be kept secure to the extent provided by law.
- We will audio and video record the discussions. To protect your privacy, only first names will be used during the group. We will keep the recordings secure and destroy them once FDA approves the report.
- Groups will be observed by study team members from Westat and FDA.
- We may use quotes from you in our report, but we will never use your name.

Risks:

- You will be asked about certain experiences you may have had taking a human drug product, but you will not be asked to disclose the name of the drug or the medical condition(s) for which you are being treated.
- Participants have been asked to be in a private location, but there is a chance that people not in the focus group may see or hear our discussion.

Benefits:

- There are no direct benefits to you for participating in this study. The results of this research will help FDA better understand consumers' experiences with prescription and over-the-counter drugs.

Questions:

- If you have questions about the project you may call the Westat Project Director, Cynthia Robins, at 610.593.7389 or 240.367.4753.
- If you have any questions or complaints about your rights as a research subject, please contact Westat's Human Subject Protections Office at 1-888-920-7631. Please leave a message with your first name, the name of the research study that you are calling about (FDA Human Drug Product Study), and a phone number beginning with the area code. Someone will return your call as soon as possible.