

Focus Group Consent Form

Key Information

- Your participation is voluntary.
- You are being asked to be part of a focus group discussion about the ways that cancer treatments are talked about in prescription drug advertisements. As part of the discussion, we will also ask you some questions about statements found in advertisements for drugs used to treat different types of cancer.
- The focus group discussion will take about one hour.
- To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

What is the Research About?

We are asking you to take part in a research study about consumers' perspectives on the ways that cancer treatments are talked about in prescription drug advertisements. If you take part in the study, you will be one of about 72 people to do so. You are being invited to participate in a research study because you may have unique insights about the ways that cancer treatments are talked about.

Who is Leading the Study?

The person in charge of this study is Vanessa Boudewyns of RTI International. This research is being conducted on behalf of the U.S. Food and Drug Administration (FDA).

What is the Purpose of This Study?

By doing this study we hope to learn more about consumers' understanding of the terms used in prescription drug advertisements for cancer treatments.

Do I Have to Take Part in this Study?

- If you decide to take part in the study, it should be because you really want to volunteer. There will be no penalty and you will not lose any benefits or rights you would normally have if you choose not to volunteer. No one on the research team will be upset if you choose not to participate in the study.
- Even if you decide to be part of the study now, you may change your mind and stop at any time.
- You also do not have to answer any questions that you do not want to. You will receive the token of appreciation for your time when you complete the study even if you choose not to answer some questions.

What Will I Be Asked to Do?

- We will ask you to participate in a group discussion (with 8-9 people) about the ways that cancer treatments are talked about in prescription drug ads. As part of the discussion, we will also ask you some questions about statements found in advertisements for drugs used to treat different types of cancer. The focus group discussion will last about **one hour**.

- We will audio record the discussions. Additionally, staff members may be viewing the focus groups in person (behind a one-way mirror) or remotely (via live video-streaming). Only first names will be used during the focus group, and any transcripts will not include your name.
- If you do not want to be audio recorded, or you do not consent to having the focus groups be live-streamed to remote staff, you will not be able to participate in the research.

What Are the Possible Risks?

- The risks associated with participating in this focus group are the same as those you would experience talking in a group of people that you do not know.
- Some parts of the focus group discussion may be considered sensitive in nature because we will be talking about cancer treatment outcomes. This topic may make some people uncomfortable or upset if they have experienced serious illness themselves or if they have had a close family member experience a serious illness. If any questions make you feel uncomfortable, you do not have to participate in that part of the discussion.
- It is also possible that others may find out that you participated in this research. RTI will take several steps to keep your participation secure to the extent provided by law.
 - RTI and FDA will not receive any record of your full name or contact information. This means that your personal information (name, address, phone number) will not be linked to any of your responses.
 - We will assign a Participant ID number so that your answers to the screener or your comments in the focus group discussion cannot be directly linked to your name.
 - All data collected during the focus group will be kept private to the extent provided by law. The study team will not disclose your name or any of your responses.
 - All data collected during the focus group will be stored in a locked file cabinet or on a password-protected computer for a period of three years and will only be accessible by RTI, after which they will be destroyed by securely shredding the documents or permanently deleting electronic information.
 - We will also be audio recording our discussion. The transcriptions and the audio recordings will be used to prepare a summary of each group's discussion. The audio files will be stored on password-protected computers and will be transcribed. During the focus group, please do not tell us anything about yourself that could be used to identify you, like your last name (it is okay to tell us your first name) or birthday. If you do tell us this information by mistake, that part of the audio recording will not be transcribed.
 - Study team members may also observe the focus group via live-streaming video. Live-streaming connections will be secure, using industry-standard firewalls and security practices. All data will be encrypted in transit using secure hypertext transfer protocol (HTTPS).

Even with these steps, there is still a small risk that your privacy could be broken.

Will I Benefit from Taking Part in This Study?

- There are no direct benefits to you for participating in this study. However, we will use the experiences and thoughts you share to improve the usefulness of prescription drug information for people like you.

Will I Receive Any Payment for Taking Part in this Study?

- You will receive \$40 for taking part in this study. You will receive this token of appreciation for your time when you complete the study even if you choose not to answer some questions.
- If you decide you do not want to be audio recorded/live streamed, you will not be able to participate in the study and you will not receive the \$40.

Who Will See the Information I Give?

- When we analyze the results, your information will be separated from the information that identifies you and combined with information from other people taking part in the study. We will write a report about all the focus groups and may use quotes from you in our report, but your quotes will be separated from the information that identifies you and combined with information from other people taking part in the study.
- You will not be identified in any published or presented materials.

Can My Data Be Kept and Used for Other Research Studies?

- Your data will not be used for any future research after this study is complete.
- You will not be contacted in the future about this research after your participation in the focus group ends.
- We plan to keep the audio recordings on a secure online server, only accessible by RTI, and to destroy them after a period of three years. However, the transcripts will be sent to FDA as part of a final report.

What If I Have Questions?

- Before you decide whether to participate in the study, please ask any questions that come to mind. Later, if you have questions about the study, you can contact the investigator, Vanessa Boudewyns at 202-728-2092. She can be reached between 9:00 AM and 5:00 PM Central Time Monday to Friday.
- The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration has reviewed this research. RIHSC is an institutional review board, a group of people who are responsible for ensuring that the rights of participants in research are protected. The RIHSC is not involved in this study but may review the records of your participation in this research to ensure that proper procedures were followed. If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact RIHSC at 1-301-796-9605 or RIHSC@fda.hhs.gov.

We will give you a copy of this document for your records.

Research Participant Statement and Signature

I understand what the study involves, and my questions so far have been answered. I understand that my participation in this research study is voluntary. I agree to take part in this focus group study.

Participant's signature

Date