

Focus Group Consent Form

Key Information

- Your participation is voluntary.
- You are being asked to be part of a focus group discussion about ways that you use and what you think about different drug devices. As part of the discussion, we will ask you to participate in group brainstorming and word association activities to help us understand your opinions of the devices. You will also be asked to hold different versions of actual prescription drug devices, and to talk about your experiences and opinions related to them.
- The focus group discussion will take about 90 minutes.
- 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 purpose of this study?

- This study is designed to learn more about consumer's perspectives on drug-device combination products like inhalers and autoinjectors.
- If you take part in the study, you will be one of about 160 people to do so. You are being invited to participate in a research study because you may have unique insights about how prescription combination products are used.

Who is leading the study?

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

Do I have to take part in this study?

- It is your choice to participate in this focus group discussion. No one will be upset if you choose not to participate.
- Even if you decide to be part of the study, you can stop participating at any time. You also do not have to answer any questions that you do not want to. You will receive payment as a token of our appreciation for your participation.

What will I be asked to do?

- We are asking you to participate in a focus group discussion (with about 8-10 people). During the discussion, we will ask you about how you use different prescription combination products and what you think about them. We will ask you to participate in group brainstorming and word association activities. You will also be asked to hold different versions of actual prescription combination products, and to talk about your experiences and opinions related to them.
- The focus group discussion will last about **90 minutes**.
- We will audio record the discussions, and the recordings will be used to create transcripts. Staff members may also be viewing the focus groups in person (behind a one-way mirror) or remotely (via

live video streaming). Only first names will be used when audio recording, 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.
- You will be asked to hold either an autoinjector or dry powder inhaler and answer some questions about the device. Neither device has any medicine in it. The autoinjector is a trainer device; it does not contain medicine or a needle and it cannot be discharged, and the dry powder inhaler does not contain medicine. We will only ask you to hold and look at the device.
- We do not expect that any of the topics discussed during the focus group will make you uncomfortable or upset you; however, if they do, you do not have to participate in that part of the discussion.
- RTI will take steps to keep your participation secure to the extent provided by law. Even with these steps, there is still a small risk that your privacy could be broken.
 - Throughout the study 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.
 - All data collected during the focus groups will be kept confidential 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.
- In addition to these steps, we have obtained a *Certificate of Confidentiality* from FDA to help protect your privacy. This Certificate provides extra protection for you and your study information and documents. The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place.

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 use of drug devices for people like you.

Will I receive any payment for taking part in this study?

- You will receive \$125 as a token of our appreciation for your participation.

Who will see the information I give?

- The transcripts will be sent to FDA as part of a final report. When we analyze the results, your information will be separated from the information that identifies you and it will be 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 we will not use your name. You will not be identified in any published or presented materials. Nothing you say will be connected with your name.

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 will keep the audio recordings on a secure online server and destroy them at the end of the study. However, the transcripts will be sent to the client as part of a final report.

What if I have questions?

- Before you decide whether or not 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 Institutional Review Board (IRB) at RTI International has reviewed this research. The IRB is an institutional review board, a group of people who are responsible for ensuring that the rights of participants in research are protected. The IRB 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 RTI's Office of Research Protection at 1-866-214-2043.

You will be given a copy of this consent form to keep and we will keep a copy with the study 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 first name

Date