

Focus Group Assent Form

Key Information

- It is your choice to be in this research study.
- We have invited you to be part of a group discussion to talk about ways that you use different prescription medication drug-device combination products (like inhalers or autoinjectors) and what you think about them. During the discussion, we will ask you to do some written activities to help us understand your opinions. 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 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.

Why are we doing this research study?

- The U.S. Food and Drug Administration (FDA) would like to hear from teens 13-17 years old about their experience using these prescription drug-device combination products (also called “combination products”), and to hear what you think about them.
- You are being invited to participate in this research study because you said you used one of these combination products, and you may have unique insights about how they are used. If you take part in the study, you will be one of about 40 people to do so.

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 FDA.

Do I have to participate in the 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 for your time when you complete the study even if you choose not to answer some questions.

What will happen in this study?

- We are asking you to participate in a discussion with 8-10 people, called a focus group. 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 we will make transcripts (a written record of what was said). Staff members working on the project might also be watching the focus groups in-person (behind a one-way mirror) or remotely (through live video streaming).
- Only first names will be used when audio recording, and any transcripts or notes from the groups will not include your name.
 - If you do not want to be audio recorded, or you do not agree to having the focus groups be live-streamed to remote staff, you will not be able to participate in the research.

What are the problems that might happen in this study?

- Sometimes people have problems in research studies that make them feel bad. The risks that might come from 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 a dry powder inhaler. 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. You will only be asked 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. It is important that you let the researchers and your parents know if there's anything you don't like about the research.
- 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 compute 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.

What are the good things that might happen in this study?

- People may have good things happen to them because they are in research studies. These good things are called "benefits." 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 combination products for people like you.

Will I get any money for being in this research study?

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

Who will be told the things you learn about me in this study?

- 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. Your name will not be in any report of the results of this study. Nothing you say will be connected with your name.

Can my data be kept and used for other research studies?

- Your information 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 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.

Who should you ask if you have any questions?

- If you have any questions, you should ask us. If later, you or your parents have questions, about the project, you may call the Project Director, 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 assent form to keep and we will keep a copy with the study records.

Do you agree to be part of this study? If you sign your first name on this page, it means you agree to take part in this research study. You may change your mind any time for any reason.

- Yes
- No

Participant's **first** name

Date

Research staff signature indicating assent

Date