

Focus Group Parent Permission Form

Key Information

- Your child's participation is voluntary.
- Your child has been asked to be part of a focus group discussion about ways that they use and what they think about different prescription drug devices, like autoinjectors or dry powder inhalers. As part of the discussion, we will ask them to participate in group brainstorming and word association activities to consider their perspectives on the devices. They will also be asked to hold different versions of actual prescription drug devices, and to talk about their experiences and opinions related to them.
- The focus group discussion will take about 90 minutes.
- To the best of our knowledge, the things your child will be asked to do in the focus group

What is the purpose of this study?

- We are asking your permission to allow your child to participate in a research study about prescription drug-device combination products (also called "combination products") like inhalers and autoinjectors. The U.S. Food and Drug Administration (FDA) would like to hear from teens 13-17 years old about their experience using these combination products
- If your child takes part in the study, they will be one of about 40 people to do so. Your child is being invited to participate in this research study because they have indicated that they use one of these combination products and may have unique insights about how they 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 FDA.

Does my child have to take part in this study?

- It is your choice to give permission for your child to take part in the study. No one on the research team will be upset if you choose not to give permission for your child to participate in the study.
- Your child also does not have to answer any questions that they do not want to. Your child will receive compensation for their time even if they choose not to answer some questions.
- Even if you decide to give your permission now, you may change your mind at any time.

What will my child be asked to do?

- If you agree to let your child participate, they will be asked to talk with about 8-10 other youth (ages 13-17) in a moderated group discussion and answer questions about their experiences using different prescription combination products (e.g., autoinjectors or inhalers) and their opinions related to these devices. We will ask them to participate in group brainstorming and word association activities. They will also be asked to hold different

versions of actual prescription combination products, and to talk about their 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. Study 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 when audio recording, and any transcripts will not include your child's name.
 - If you do not want your child to be audio recorded, or you do not consent to having the focus groups be live-streamed to remote staff, your child 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 your child might experience talking in a group of people that they do not know.
- Your teen 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 cannot be discharged, and the dry powder inhaler does not contain medicine. Your teen 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 your child uncomfortable or upset them; however, if they do, your child does not have to participate in that part of the discussion.
- RTI will take several steps to keep your child's 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 yours or your child's full name or contact information. This means that your child's personal information (name, address, phone number) will not be linked to any of their 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, your child's name, or any of their 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 your child and their study information and documents. The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about your child as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your child's study information without their consent. This is a layer of protection over and above the already existing protections in place. All your child's information will be kept secure to the extent provided by law.

Will my child benefit from taking part in this study?

- Your child will not personally benefit from taking part in this study. However, we will use the experiences and thoughts your child shares to improve the use of combination products for people like them.

Will my child receive any payment for taking part in this study?

- Your child will receive \$125 for taking part in this study.

Who will see the information they give?

- The transcripts will be sent to FDA as part of a final report. When we analyze the results, your child's information will be separated from the information that identifies them 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 your child in our report, but we will not use their name. Nothing they say will be connected with their name.

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

- Your child's data will not be used for any future research after this study is complete.
- You or your child will not be contacted in the future about this research after their 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.

What if I have questions?

- Before you decide whether or not to give permission for your child 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 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.

Parent/Legally Authorized Representative Permission Statement and Signature

I understand what the study involves, and my questions so far have been answered. I understand that permitting my child's participation in this research study is voluntary. I agree to let my child take part in this study.

Parent's or Guardian's Printed Name

Date

Parent's or Guardian's Signature