Focus Group Parent Permission Form

**Key Information**

* Your child’s participation is voluntary.
* Your child has been asked to be part of an online (virtual) focus group discussion about ways that they use and what they think about prescription drug devices, like autoinjectors. As part of the discussion, we will ask them to participate in some activities to help us understand 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 devices will have no medicine or needles in them.)
* The virtual 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 will be doing have no more risk of harm than your child would experience in everyday life.

### 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 devices like autoinjectors. The U.S. Food and Drug Administration (FDA) would like to hear from teens 12-17 years old about their experiences using these drug devices to treat their medical conditions.
* If your child takes part in the study, they will be one of about 50 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 devices 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 6 other youth (ages 12-17) in a moderated online group discussion using an Internet platform called Zoom. Connecting to the platform is free.
	+ You and your child will be provided instructions for joining the discussion and protecting your child’s identity. Only first names will be used.
* During the discussion, your child will be asked questions about their experiences using their autoinjector) and their opinions related to these devices. We will ask them to participate in group brainstorming activities. They will also be asked to hold different versions of actual prescription autoinjectors and talk about their experiences and opinions related to them. The autoinjectors will contain no medicine or needles.
* Your child will be in a Zoom meeting with an interviewer, a notetaker, and a few other people their age. In addition to the interviewer, it is also possible that a few other research team members may observe the discussions so they can hear your child’s opinions directly from them. However, they will not be visible, and they will not interact with your child or the interviewer.
* The focus group discussion will last about **90 minutes**.
* The organization that recruited your child to participate will ask for your contact information to mail your child a package of materials that they will need for the study. The package will include instructions, an activity sheet, and the autoinjector devices they will handle during the discussion. **You and your child will be instructed to not open the package until after the focus group discussion begins.**
* We will video and audio record the discussions, and the recordings will be used to create transcripts. Staff members working on the project who were unable to watch the live streaming of the focus group will have access to the recording of the focus group via a password-protected link for a limited time after the discussion.
* If you do not want your child to be video and 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 child will be asked to hold an autoinjector and answer some questions about the device. The autoinjectors are trainer devices that contain no medicine or needle and cannot be discharged. Your child 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.
* The organization that recruited your child to be part of the study will ask for your contact information to send your child a package of materials they will need for the discussion. None of this information will be provided to RTI or FDA.
* 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 on a secure server. In addition, all data transfers are protected by encryption.
* 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.

### 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 drug devices 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 video and audio recordings on a secure online server and destroy them at the end of the study. However, the transcripts will be sent to the FDA 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.

### Research Participant Agreement [to be included in digital permission sent in advance by the recruiter]

If you read the information above and agree to give permission for your child to participate, please check the Yes button.

[ ]  Yes, I give my permission for my child to participate.

[ ]  No, I do not give my permission for my child to participate.