Focus Group Assent Form

Key Information

- It is your choice to be in this research study.
- We have invited you to be part of an online (virtual) group discussion to talk about ways that you use prescription medication devices, like autoinjectors and what you think about them.
- During the discussion, we will ask you to do some activities to help us understand your opinions. You will also be asked to hold different versions of actual prescription medication devices, and to talk about your experiences and opinions related to them. (The devices will have no medication in them.)
- The virtual 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 study is designed to learn from adolescents12-17 years old about their experience using prescription medication devices (also called "drug devices"), and to hear what you think about them.
- You are being invited to participate in this research study because you and your parent or guardian said you used one of these devices, and you may have unique insights about how they are used. If you take part in the study, you will be one of about 50 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 Food and Drug Administration (FDA).

Do I have to participate in the study?

- It is your choice to participate in this virtual 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 focus group discussion with about 6 other people your age conducted online through an Internet platform called Zoom. Connecting to the platform is free.
    - You will be provided instructions for joining the discussion and protecting your identity. Only first names will be used.
- You will be in a Zoom meeting with an interviewer, a notetaker, and a few other people your age who are also participating in the discussion. In addition to the interviewer, who you will see onscreen, it is also possible that a few other research team members may observe the discussions so they can hear

your opinions directly from you. However, they will not be visible, and they will not interact with you or the interviewer.

- During the discussion, we will ask you about how you use different autoinjector devices and what you think about them. We will ask you to participate in group brainstorming activities. You will also be asked to hold different versions of actual autoinjector drug devices, and to talk about your experiences and opinions related to them. These autoinjectors contain no medicine or needles
- The focus group discussion will last about **90 minutes.**
- The organization that recruited you to participate will ask for your contact information to mail you a package of materials that you will need for the study. The package will include instructions, an activity sheet, and the devices that you will review during the discussion. **You will be instructed to not open the package until after the focus group discussion begins.**
- We will video and audio record the discussions, and we will make transcripts (a written record of what was said). Only first names will be visible in the meeting and only first names will be recorded. 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 to be video and 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 discussion 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 an autoinjector. The autoinjector is a trainer device; it does not contain medicine, or a needle and it cannot be discharged. 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.
    - The organization that recruited you to be part of the study will ask for your contact information to send you a package of materials you 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 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 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 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 drug devices 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 from the focus group 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 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 FDA 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.

Research Participant Agreement ***[to be included in digital consent sent in advance by the recruiter]***

If you read the information above and agree to participate, please check the Yes button.

☐ Yes, I agree to participate. ☐ No, I do not agree to participate.