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Adolescent Virtual Focus Group Screening Questionnaire Prescription Drug Device Perspectives

Hello, this is _____ from [RECRUITMENT FIRM NAME], a local market research firm. May I please speak to _____?

[Speaking to parent/guardian]

Hello, my name is _____ and I'm from [NAME OF RECRUITMENT FIRM]. I'm calling on behalf of RTI International, a nonprofit research organization, about a research study sponsored by the Food and Drug Administration, or FDA. We are recruiting online focus group participants, specifically preteens and teens ages 12-17 who use prescription drug devices like auto-injectors, to discuss their experiences with using this prescription drug device. FDA believes it is important to get feedback from many people, including teens, about these devices and to understand how people use them and what they think about them. We are not selling any products.

We are holding an online focus group using Zoom on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. The study involves participating in a one-time focus group discussion with about 6 adolescents who also use prescription drug devices. During the discussion, we will talk with your child about their experiences using the drug device, and we will ask the group to share their opinions about the device. Your teen will also be asked to hold a sample auto-injector and answer some questions about the device. This device will contain no medicine and no needle.

If your child is scheduled to participate, we will mail you a package of materials for them to use during the online focus group discussion that will include two auto-injector trainer devices. The trainers will not contain medicine or a needle and cannot be discharged. We will instruct participants only to hold and look at the device. The focus group will be video and audio recorded, and project team members may also join to observe the discussion. Your teen will be given \$125 as a token of our appreciation for their participation.

First, are you the parent or guardian of a child between the ages of 12 and 17?

- Yes
 No – **Thank and end call.**

Read: An auto-injector is a medical device designed to deliver a dose of a particular prescription drug. Most **auto-injectors** are spring-loaded syringes that include a needle to inject the medicine.

1. Do any of your children between the ages of 12 and 17 have a current prescription from a doctor for an auto-injector? [If needed: refer to list of auto-injectors]
₁ Yes → **Continue to Q2**
₂ No → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT].**
2. How many of your children between the ages of 12 and 17 have a current prescription from a doctor for an auto-injector?
 1 → **Continue to Q4**
 More than 1 → **Continue to Q3, below**
3. Is your oldest child who has a prescription for an auto-injector available to see if they qualify for this study?
 Yes → **Continue to Q4**
 No → **Ask if the next-oldest child would be available. If no children are available, ask for a time to call back**

Auto-injector Brand Names (Epipen User Group Qualification)

4. What is the brand name of the auto-injector your child uses? [Refer parent to oldest available child if necessary. DO NOT READ LIST.] [Note: if a brand is NOT listed below and the participant is confident it is an auto-injector, assign them as a **hold** and contact RTI]

Participant must mention an auto-injector from this list to be included

- ADRENACLICK → **PLACE ON HOLD**
 AUVI-Q → **Terminate**
 EPIPEN → **CONTINUE**
 EPIPEN JR. → **CONTINUE**
 Epinephrine Injection USP (auto-injector) → **CONTINUE**
 “GENERIC ADRENACLICK” → **PLACE ON HOLD**
 “GENERIC EPIPEN” / “GENERIC EPIPEN JR” → **CONTINUE**

If your child qualifies, we will need you to sign a permission form prior to their participation in the focus group.

If your child qualifies, I will ask to speak to you again at the end of the call so that I can give you more information.

Before I ask to speak with your child, I have a few final questions. When I do speak with your child, I'd like you to ask them to go sit somewhere that's quiet and private, where no one else can hear their answers.

[IF PARENT QUESTIONS THE NEED FOR PRIVACY, SAY:]

We have a rule that everyone who participates in our research is assured privacy to the extent permitted by law, including children.

[READ] Before we continue, I need to confirm a couple of things.

5. Do I have permission to speak with your child to see if they qualify to participate in the study?
 Yes → **Continue**
 No → **Terminate**

6. Are you this child's parent or legal guardian?
 Yes → **Continue**
 No → **Terminate**

7. If your child qualifies for the study and decides to participate, the focus group will be audio recorded and live-streamed (via a secure connection) for study staff who will observe remotely. Can we video and audio record your child's participation in the focus group?
 Yes → **Continue**
 No → **Terminate**

Thank you. Please give the phone to your child and give them privacy for the discussion. By privacy, I mean that you are not listening to our discussion in person (i.e., you are not in the same room as or within hearing distance of your child) or over the telephone.

Teen Introduction:

Hello, this is _____ from **[NAME OF RECRUITMENT FIRM]** a local market research firm. We are working with RTI International, a nonprofit research organization, on a research study funded by the Food and Drug Administration, or FDA. This study is about the experiences of preteens and teens who use epinephrine auto-injectors, often called EpiPens. FDA believes it is important to get feedback from many people, including teens, about these devices and to understand how people use them and what they think about them. We are not selling any products.

The study involves participating in a one-time online focus group discussion with about 6 preteens and teens who also use EpiPens. The focus group will last no longer than 90 minutes. During the discussion, we will talk with you about your experience using the EpiPen, and we will ask the group to share their opinions about the EpiPen. If you agree to participate, we will mail you a package of materials to use during the online focus group discussion. The package will include two auto-injector trainer devices that have no medicine or needles in them. During the online focus group discussion, you will be asked to hold the auto-injectors and answer some questions about them.

The focus group will be video and audio recorded, and a small number of study staff may observe the focus group online. No one else will be able to see or hear the focus group. If you participate in the focus group, you will receive **\$125** as a token of our appreciation for your participation.

To see if you qualify for this study, I need to ask you some questions that will take a few minutes. Your parent/guardian gave me permission to ask you these questions. If you qualify for the study and are asked to participate, you can decide if you want to be a part of the study. If you do qualify and you

decide to participate, I will need your email address and/or phone number to contact you to remind you about your appointment. I will also need your mailing address to send you the package of materials for the focus group discussion.

All of your answers will be kept private. We won't share any of your answers with your parents or tell them why you did or didn't qualify for the study. If you do participate in the study, we won't share anything that you say during the focus group with your parents. Your contact information will be kept apart from your answers to these questions. If you feel uncomfortable at all, you can choose not to answer one or more questions or end the call at any time. However, without knowing your answers to some of the questions, we may not be able to tell if you qualify for this study. Also, just because your parent/guardian gave us permission to ask you these questions, it does not mean you have to answer them.

8. Can I ask you a few questions now to see if you qualify?

- Yes - **Continue.**
- No - **Thank the child and end call.**

9. How old were you on your last birthday? [ENTER ACTUAL AGE. Recruit mix of 12 to 17 years old]

- Younger than 12 → **Terminate**
- 12-17 → **Continue**
- 18 or older → **Recruit using adult screener**

10. What is your gender? [RECRUIT A MIX]

- Male
- Female
- Prefer not to answer

11. Are you Hispanic, Latino/a, or of Spanish origin? [RECRUIT A MIX]

- No
- Yes
- Prefer not to answer

12. What is your race? [READ LIST IF NECESSARY AND RECRUIT A MIX]

- White
- Black or African American
- Asian
- Native Hawaiian or Other Pacific Islander
- American Indian or Alaskan Native
- Prefer not to answer**

13. We will need to send you a package of materials for you to use during the online focus group discussion. Can you provide a mailing address where you can receive these materials?

- Yes → **Continue**
 No → **Thank the child and end call.**

14. The focus group will be audio recorded and the video will be live streamed to a small group of study team members. You will be asked to keep your video on during the focus group discussion. Are you okay with us recording and live streaming the focus group?

- Yes - **Continue.**
 No - **Thank the child and end call.**

15. Finally, during the online focus group discussion, you will be asked to review written materials and offer your opinions, so I need to ask, "Do you have a medical or nonmedical condition that affects your ability to read or understand written materials in English?"

- Yes → **Thank the child and end call.** No → **Continue**

16. Would you like to participate in a focus group on [DATE] at [TIME]?

- Yes - **Continue.**
 No - **Thank the child and end call.**

17. Because you are under age 18, we will need a parent's or guardian's permission for you to be in the focus group. Will you be able to have a parent or a guardian sign a form giving you permission?

- Yes - **Continue.**
 No - **Thank the child and end call.**

I will email a permission form to your parent or guardian that they need to sign before the focus group. If they don't sign the permission form, you won't be able to participate. I will also send your parent or guardian a confirmation letter and more information about the online focus group.

We are only inviting a few people, so it is very important that you let us know as soon as possible if you will be unable to attend the focus group. Please call [INSERT INFO] if this should happen. We look forward to seeing you on [DATE] at [TIME].

Parent Information for Adolescents Scheduled to Participate:

Now, I would like to give your parent/guardian the information that I just gave you about the focus group. Please put them back on the phone.

Instructions to the Parent/Guardian:

Your child is eligible to participate in the focus group and has been scheduled to participate on [DAY], [DATE] at [TIME]. Please sign in online 10 minutes before this time.

May I please have your mailing address, e-mail address, and telephone number? We will use this information to mail you a package containing focus group materials. We will also e-mail you with instructions on how to prepare for the online focus group on [DATE/TIME].

Because your child is under 18, we must get signed permission from you in order for them to participate. We will send you an email with a permission form to review and sign if you consent to your child's participation. I will also send you the informed consent form. Please have your child read the form

carefully and reply indicating whether they agree or decline to participate. They won't be able to participate unless we get their response.

We will send you a package containing focus group materials, which you can set aside until the day of the focus group. Please look for this package within the next [TIME FRAME] days. If you do not receive the package in the next [X] days, please contact us. Your child will be given \$125 as a token of appreciation for their participation.

I will call you a day or two before your child's scheduled focus group to remind you. If you need to reschedule or cancel your child's appointment to participate, please contact me at <email; phone>. We will destroy all contact information at the conclusion of the focus groups. [VERIFY CONTACT INFORMATION]

Closing Scripts

Ineligible - Closing Script

I'm sorry, but [your child is not/you are not] not eligible for this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

****NOTE** THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUPS.**

NAME: _____

ADDRESS: _____

CITY: _____

ZIP CODE: _____

E-MAIL _____

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: _____

BEST PHONE NUMBER: _____

Is there another time and number we can try if we miss you?

ALTERNATE TIME: _____

ALTERNATE PHONE NUMBER: _____

Thank you. That's all the questions I have today. If you have any questions or if your child can no longer attend, please call [recruiter's phone number] as soon as possible. Thank you again for your time. We look forward to seeing your child at [TIME] on [DATE].