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Adolescent Focus Group Screening Questionnaire Prescription Drug Device Perspectives

	Minneapolis, MN (Midwest)	Atlanta, GA (South)	Bethesda, MD (East)	Phoenix, AZ (West)	Total
Epi-pen AI User	1		1		2
Advair Diskus DPI User		1		1	2
Total	1	1	1	1	4

Note. We will recruit 10 individuals per focus group with the expectation that 8 participants are present for each session

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, on a research study sponsored by the Food and Drug Administration, or FDA. We are recruiting focus group participants, specifically teens ages 13-17 who use prescription drug devices like autoinjectors or dry powder inhalers, to discuss their experiences of 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.

The study involves participating in a one-time focus group discussion with about 8-10 teens who also use prescription combination products. The focus group will last no more than 90 minutes. During the discussion, we will talk with your child about their experiences using the combination product, and we will ask the group to share their opinions about the device. Your teen will also 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. We will instruct participants only to hold and look at the device. The interview will be audio recorded and live streamed for study staff who will observe remotely. 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 13 and 17?

Yes

No - **Thank and end call.**

Autoinjector Use

1. Do any of your children between the ages of 13 and 17 have a current prescription from a doctor for an autoinjector? [If needed: refer to list of autoinjectors]

₁ Yes → **Continue to Q2**

₂ No → **Continue to Q4**

2. How many of your children between the ages of 13 and 17 have a current prescription from a doctor for an autoinjector?

1 → **Continue to Q4**

More than 1 → **Continue to Q3, below**

3. Is your oldest child who has a prescription for an autoinjector 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 time to call back**

Dry Powder Inhaler Use

4. Do any of your children ages 13-17 have a current prescription from a doctor for a dry powder inhaler? [If needed: Dry powder inhalers are devices that deliver medication to the lungs and are usually used to treat respiratory diseases such as asthma, bronchitis, emphysema and COPD]. [If needed: refer to list of dry powder inhalers]

₁ Yes → **Continue to Q5**

₂ No → **IF Q1=2, TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]. IF Q1=1, Continue to Q9**

5. How many of your children ages 13-17 have a current prescription from a doctor for a dry powder inhaler?

₁ 1 → **Continue to Q7**

₂ More than 1 → **Continue to Q6**

6. Is your oldest child who has a prescription for a dry powder inhaler available to see if they qualify for this study?

₁ Yes → **Continue to Q7**

₂ No → **Ask if the next-oldest child would be available. If no children are available, ask for time to call back**

Dry Powder Inhaler Brand Names (Advair Diskus DPI User Group Qualification)

7. Why does your child need the inhaler (what is their diagnosis) [Refer parent to oldest available child if necessary]?

8. What is the brand name of the dry powder inhaler your child currently uses? [Refer parent to oldest available child if necessary. DO NOT READ OPTIONS. Refer to dry powder inhaler list. NOTE BRAND NAME]

₁ If Advair Diskus → **IF Q1=1, Continue to Q9 as Potential Advair Diskus DPI User Group / IF Q1=2, ASSIGN TO Advair Diskus DPI User Group**

₂ All others → **IF Q1=1, Continue to Q9 as Potential Epi-Pen User Group / IF Q1=2, TERMINATE**

Autoinjector Brand Names (EpiPen User Group Qualification)

9. What is the brand name of the auto injector your child uses? [Refer parent to oldest available child if necessary. DO NOT READ LIST. Refer to autoinjector list]

EpiPen, EpiPen Jr., Epinephrine Injection USP → **IF Q4=1 AND Q8=1, ASSIGN TO EITHER THE EpiPen User group OR Advair Diskus DPI User Group based ON WHICHEVER HAS FEWER CONFIRMED PARTICIPANTS / IF Q4=2 ASSIGN TO EpiPen User Group**

All others (not EpiPen, EpiPen Jr., Epinephrine Injection USP) → **IF Q4=1 AND Q8=1, ASSIGN TO Advair Diskus DPI User Group / IF Q4=2, TERMINATE / IF Q4=1 AND Q8=2, TERMINATE**

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 we do speak with them, 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.

10. Do we have permission to we speak to your child to see if they qualify to participate in the study?

- Yes → **Continue**
 No → **Terminate**

11. Are you this child's parent or legal guardian?

- Yes → **Continue**
 No → **Terminate**

12. If your child qualifies for the study and decides to participate, the interview will be audio recorded and live-streamed (via a secure connection) for study staff who will observe remotely. Can we audio record and live stream 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, on a study about the experiences of teens who use **[INSERT SEGMENT – EPIPENS OR DRY POWDER INHALERS]**. 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 focus group discussion with about 8-10 teens who also use prescription combination products. The focus group will last no longer than 90 minutes. During the discussion, we will talk with you about your experience using the combination product, and we will ask the group to share opinions about the device. You will also 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. We will only ask you to hold and look at the device.

The interview will be audio recorded and live-streamed for study staff who are observing remotely. 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 are asked and decide to participate, I will need your parent or guardian's email address and/or phone number to contact them to remind them about your appointment.

All of your answers will be kept secure to the extent provided by law. 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 interview with your parents. Your parent or guardian's 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 does not mean you must answer them.

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

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

14. How old were you on your last birthday? [ENTER ACTUAL AGE. Recruit mix of 13 to 17 years old]

- Younger than 13 → **Terminate**
- 13-17 → **Continue**
- 18 or older → **Recruit using adult screener**

15. Have you participated in an interview or focus group in the past 6 months? [READ LIST]

- Yes → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
- No → **Continue**

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

- Male
- Female
- Prefer not to answer

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

- No
- Yes

18. 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**

19. The focus group will be audio recorded and the video will be live streamed to study team members. Are you okay with us audio recording and live streaming the focus group?

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

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

- Yes → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
 No → **Continue**

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

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

22. 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 send a permission form to your parent or guardian that you will need to bring with your parent's or guardian's signature when you come to the focus group. If you don't have this permission form, you won't be able to participate. I will also send your parent or guardian a confirmation letter and directions to the place where we will hold the focus group.

We are only inviting a few people, so it is very important that you let us know as soon as possible if for some reason you are unable to attend. Please call [INSERT INFO] if this should happen. We look forward to seeing you on [DATE] at [TIME]. If you normally wear glasses or hearing aids, please remember to have them with you.

Parent Information for Adolescents Scheduled to Participate:

Now, I would like to give your parent/guardian this 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 arrive 15 minutes before this time. Because your child is under 18, we must get written permission from you in order for them to participate. We will be sending you a permission form to review and sign if you consent to your child's participation. If you will be accompanying your child to the focus group, please bring this completed form with you. If you are unable to accompany your child, they must bring the signed permission form in order to participate. Your child will be given **\$125 as a token of appreciation** for their participation.

I will also send you a confirmation letter and directions to the place where we will hold the focus group. In order to do so, please verify your mailing address and phone number where you can be reached. We are asking for your contact information only to send you a reminder letter and giving you a call to remind you of the discussion group. We will destroy all personal information when we finish the focus group.

[Refer to this List of auto-injectors]

ADRENACLICK
ATROPEN
AUVI-Q
BYDUREON BCISE
DUODOTE

EPIPEN
EPIPEN JR.
EVZIO
IMITREX STATdose
OTREXUP
RASUVO
XYOSTED
ZEMBRACE SymTouch
Epinephrine Injection USP (autoinjector)
Sumatriptan Injection USP (autoinjector)

[Refer to this List of brand name DPIs]

ADASUVE
ADVAIR DISKUS
AFREZZA
AIRDUO RESPICLICK
ANORO ELLIPTA
ARCAPTA NEOHALER
ARIDOL
ARMONAIR RESPICLICK
ARNUITY ELLIPTA
ASMANEX TWISTHALER
BREO ELLIPTA
FLOVENT DISKUS
FORADIL AEROLIZER
INCRUSE ELLIPTA
PROAIR RESPICLICK
PULMICORT FLEXHALER
RELENZA
SEEBRI NEOHALER
SEREVENT DISKUS
SPIRIVA HANDIHALER
TOBI PODHALER
TRELEGY ELLIPTA
TUDORZA PRESSAIR
UTIBRON (NEOHALER)

Closing Scripts

Ineligible - Closing Script

I'm sorry, but [your child/you] are 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].