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Adult Virtual Focus Group Screening Questionnaire Prescription Drug Device Perspectives

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

Hello. We are working with RTI International, a nonprofit research organization on a research study sponsored by the Food and Drug Administration, or FDA. We are recruiting online focus group participants 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 about these devices, and we would like to get your opinions and hear about your experiences using an autoinjector. We are not selling any products.

During the focus group, you will also be asked to hold an autoinjector and answer some questions about the device. If you are scheduled to participate, we will mail you a package of materials for you to use during the online focus group discussion. The package will include two autoinjectors. The autoinjectors will be trainer devices and will not contain medicine or a needle and cannot be discharged. You will be only be asked to hold and look at the device.

We are holding an online focus group using Zoom on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. The discussion will be video and audio recorded, and project team members may also join to observe the discussion. You will be given \$125 as a token of our appreciation for your participation.

May I ask you a few questions to see if you qualify?

Yes - **Continue.**

No - **Thank and end call.**

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

1. Do you have a current prescription from a doctor for an autoinjector?

- ₁ Yes
- ₂ No

2. Do you take care of someone in your family who has a current prescription from a doctor for an autoinjector?

- ₁ Yes → IF Q1=YES, Continue to Q3, IF Q1=NO, Continue to Q4
- ₂ No → IF Q1=NO, TERMINATE, IF Q1=YES, CONTINUE TO Q3

3. IF Q1=YES, ASK → What is the brand name of the autoinjector you use? [DO NOT READ LIST] [Note: if a brand is NOT listed below, and the participant is confident it is an autoinjector, assign them as a hold and contact RTI]

Participant must mention an autoinjector from this list to be included

- ADRENACLICK → TERMINATE
- AIMOVIG → TERMINATE
- ATROPEN → TERMINATE
- AUVI-Q → TERMINATE
- AVONEX PEN → TERMINATE
- BYDUREON BCISE → TERMINATE
- EPIPEN → ASSIGN TO EpiPen User group
- EPIPEN JR. → ASSIGN TO EpiPen User group
- EVZIO → TERMINATE
- IMITREX STATdose → TERMINATE
- OTREXUP → TERMINATE
- RASUVO → TERMINATE
- REBIF / REBIJECT → TERMINATE
- SURECLICK, ENBREL → TERMINATE
- XYOSTED → TERMINATE
- ZEMBRACE SymTouch → TERMINATE
- Epinephrine Injection USP (autoinjector) → ASSIGN TO EpiPen User group
- Sumatriptan Injection USP (autoinjector) → TERMINATE
- Both an EpiPen, EpiPen Jr., Epinephrine Injection USP AND another AI → ASSIGN TO EpiPen User group

4. IF Q2=YES, ASK → What is the brand name of the autoinjector your family member uses? [DO NOT READ LIST]

- EpiPen, EpiPen Jr., Epinephrine Injection USP → ASSIGN TO EpiPen Caregiver group
- All others → TERMINATE IF THEY DO NOT QUALIFY FOR THE EPIPEN USER OR OTHER AI USER GROUPS

[If someone qualifies for multiple groups, assign them to whichever group has fewer confirmed participants]

Market Research Exclusion

5. Have you ever worked for ...? [READ LIST]

- Any office, division, or agency within the Department of Health and Human Services (HHS) → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
- A pharmaceutical company → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
- A marketing or market research company → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
- A healthcare company or in the healthcare field → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**
- A medical device company → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

6. Have you participated in an interview or focus group in the past 3 months? [READ LIST]

- Yes → **ASK 6A.**
- No → **Continue**

IF Q6=YES, ASK 6A. Was the focus group related to prescription or over-the-counter medicines or did it have anything to do with your medical condition?

- Yes → **TERMINATE [MAKE NOTE OF THE TOPIC AND GO TO INELIGIBLE CLOSING SCRIPT]**
- No → **MAKE NOTE OF THE TOPIC AND MONTH AND Continue to Q7**

Demographics

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

- Male
- Female
- Prefer not to answer

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

- No
- Yes
- Prefer not to answer

9. 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**

10. What is the highest level of education that you have completed? [RECRUIT A MIX]

- Less than high school diploma
- High school graduate or GED
- Some college or 2-year degree
- College degree
- Postgraduate degree

11. We 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 → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

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

13. For study purposes, the online focus group will be recorded and the video will be live streamed to study team members. If you participate, 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 → **TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]**

Closing Scripts

Ineligible - Closing Script

I'm sorry, but 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.

Eligible - Closing Script

Great! You qualify for our study. The virtual discussion group will be held on [DATE] at [TIME] and will last about 90 minutes. You will receive \$125 as a token of our appreciation for your participation.

Would you like to participate in the group discussion at [TIME] on [DATE]?

- Yes - **Continue to scheduling script.**
- No - **Thank the adult and end call.**

Eligible - Scheduling script

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 about how to prepare for the online focus group on [DATE/TIME].

I will also send you an email with the informed consent form for the study. Please read the form carefully and reply indicating whether you agree or decline to participate. You won't be able to participate unless we get your response.

We will send you a package containing focus group materials, which you can set aside until the day of your 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.

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

Follow-up

****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 find that you are unable to attend, please call [recruiter's phone number] as soon as possible. Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].