Appendix A

Cognitive Interview Recruitment and Screener Scripts

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Any text in curly brackets "{ }" indicates part of the script that will change based on the participant, or situation. The intended content (or content options) is indicated in the brackets.

Email Invitation

Subject: Interview for FDA Study on Selecting Prescription Drugs

Dear **{NAME}**:

Schlesinger Group, an international marketing research company, is conducting a very interesting study sponsored by the U.S. Food and Drug Administration and would very much like to include your opinions. What we learn from the interviews will help the FDA improve a survey being developed to understand how people make decisions about prescription drugs and will help advance research for the public good.

First, we need to ask you a few questions to see if you fit the criteria for an upcoming research study. If your answers are appropriate to the study, you will be called to complete your screening.

Reference #: {Project #}
Study Topic: Prescription Drug Decision Making
Study Date(s): {DATES}
Study Location(s): Online video interview
Study Duration: 60 minutes
Study Incentive: $50 e-gift card as a token of appreciation

Additional Notes:

If you are interested in participating, please click the link, or copy and paste the following address into your Internet browser to get started.

Link: {Link to Web Screener}

If your answers are appropriate to the study, you will be called to complete your screening. Qualified respondents who are invited and participate in the research will be compensated for their time.

Please note: *Completion of the survey does not constitute confirmation for participation. If you are selected to participate, you will be contacted by one of our team members to complete the screening process and confirm your participation. This survey is for market research purposes only. There will be no direct sales or promotions as a result of your participation. Your individual responses will be kept confidential and anonymous and*

reported only in the aggregate.

Thank you! Help us learn today and you'll be the first in line to earn in the future!

{Signature line with phone number and email}

Email Follow-Up to Non-Respondents

Subject: Participants Needed for Research Study

{Forward previous email}

Dear **{NAME}:**

I am from Schlesinger Group, and I recently sent an email inviting you to participate in an interview. As a reminder, we are conducting online video interviews to get opinions about a survey being developed to study how people select medical treatments.

Your input is important, and your participation is greatly appreciated. If you are eligible and agree to participate, you will receive a token of appreciation valued at $50 after the interview is complete and the project has concluded. If you are interested in participating, please click the link below to complete a brief screener by **{DATE}.** If you have any questions about the study, or prefer to complete the screening by phone, I can be reached at **{EMAIL/PHONE}.**

{Link to Screener}

Kind regards,

{Signature line with phone number and email}

Web Screener

[PROGRAMMING NOTE: Include the OMB control number/expiration date and PRA statement as a footer at the bottom of first screen:

OMB Control No. XXXX-XXXX
Expiration date: MM/DD/YYYY

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is XXXX-XXXX and the expiration date is MM/DD/YYYY. The time

required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

]

Introduction

Thank you for your interest in this study sponsored by the U.S. Food and Drug Administration. Please answer the following questions to see if you are eligible to participate in an online video interview about a survey being developed to understand the factors people consider when selecting medical treatments.

The interviews will be led by a researcher through an online video platform. If you're eligible, you can participate from home using a computer and web camera. The discussion will last about 60 minutes, and you will receive a token of appreciation valued at $50 once the sessions are finished, and the project has concluded.

To determine your eligibility for this study, we need to ask you a few questions. These questions should take no more than 5 minutes.

Would you like to continue?

| **Yes** | | ➔ **CONTINUE** |
| **No** | | ➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT** |

Include the OMB control number/expiration date as a footer at the bottom of all screens after the first:

OMB Control No. XXXX-XXXX
Expiration date: MM/DD/YYYY
]

1. If you are eligible and agree to participate, do you consent to having your interview audio and video recorded?

Yes		➔ **CONTINUE**
No		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

2. Do you consent to having your interview livestreamed?

Yes		➔ **CONTINUE**
No		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

3. What is your current age?

_____	➔ **IF Q1 < 18, TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

4. Do you read and speak English fluently?

Yes		➔ **CONTINUE**
No		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

5. Have you participated in an interview or focus group during the past three months?

Yes		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
No		➔ CONTINUE

6. Do you currently work in any of the following occupations?

Medical Doctor		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
Any Other Type of Health Care Provider (Nurse, Physician Assistant)		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
None of the above		➔ CONTINUE

7. Do you currently work for any of the following organizations? (Occasional consulting is acceptable)

US Department of Health and Human Services		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
Pharmaceutical Company		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
Market Research Firm		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
RTI International		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**
None of the above		➔ CONTINUE

8. Have you ever been diagnosed by a health care provider with any of the following conditions? (Select all that apply).

Allergies		→ **TERMINATE** (if Type 2 Diabetes or Psoriasis not selected)
Asthma		→ **TERMINATE** (if Type 2 Diabetes or Psoriasis not selected)
Chronic Pain		→ **TERMINATE** (if Type 2 Diabetes or Psoriasis not selected)
High Blood Pressure		→ **TERMINATE** (if Type 2 Diabetes or Psoriasis not selected)
Plaque psoriasis		→ CONTINUE
Type 2 Diabetes		→ CONTINUE
IF NEITHER DIABETES NOR PLAQUE PSORIASIS SELECTED → **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT** **SCREEN FOR 50:50 MIX**		

9. **{IF PLAQUE PSORIASIS SELECTED FOR Q7}** Are you currently receiving treatment for plaque psoriasis? Treatment may include a medication or a cream or ointment.

Yes		→ **CONTINUE**
No		→ **CONTINUE**

10. **{IF TYPE 2 DIABETES SELECTED FOR Q7}** Are you currently receiving treatment for type 2 diabetes? Treatment may include insulin or another medication.

Yes		→ **CONTINUE**
No		→ **CONTINUE**

These interviews will take place via web-based video conferencing. The next few questions will involve technology – please answer these questions <u>considering the location and computer you will be joining the interview from</u>.

11. Do you have access to a reliable, high-speed Internet connection (i.e., DSL or broadband) at the location you will be joining the interview from?

Yes		➔ CONTINUE
No		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

12. What type of computer will you be using to join the interview?

PC laptop or desktop		➔ CONTINUE
Mac laptop or desktop		➔ CONTINUE
Tablet or mobile device		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

13. Do you have a webcam installed or connected to your PC/MAC laptop or desktop?

Yes		➔ CONTINUE
No		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

14. What is your gender?

Male		➔ CONTINUE
Female		➔ CONTINUE
Prefer not to answer		➔ CONTINUE
SCREEN FOR A MIX		

15. Are you Hispanic or Latino?

Yes		➔ CONTINUE
No		➔ CONTINUE
SCREEN FOR A MIX		

16. What is your race? Please select all that apply. [Read options below]

American Indian or Alaska Native		➔ CONTINUE
Asian		➔ CONTINUE
Black or African American		➔ CONTINUE
Native Hawaiian or Other Pacific Islander		➔ CONTINUE
White		➔ CONTINUE
SCREEN FOR A MIX		

17. In what state do you currently live?

_____		➔ CONTINUE
SCREEN FOR A MIX BASED ON THE FOLLOWING REGIONS:		

Northeast: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, and Pennsylvania

South: Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, Washington D.C., West Virginia, Alabama, Kentucky, Mississippi, and Tennessee, Arkansas, Louisiana, Oklahoma, and Texas

Midwest: Illinois, Indiana, Michigan, Ohio, Wisconsin, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota

West: Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming, Alaska, California, Hawaii, Oregon, and Washington

18. What is the highest degree or level of school you have completed?

1. **Less than high school**		➔ **CONTINUE**
2. **High school graduate or GED**		➔ **CONTINUE**
3. **Some college but no degree**		➔ **CONTINUE**
4. **Associate degree (for example: AA, AS)**		➔ **CONTINUE**
5. **Bachelor's degree (for example: BA, BS)**		➔ **CONTINUE**
6. **Postgraduate or advanced professional degree (for example: MA, MS, PhD, MD, DDS, JD)**		

19. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

1. **Never**		➔ **CONTINUE**
2. **Rarely**		➔ **CONTINUE**
3. **Sometimes**		➔ **CONTINUE**
4. **Often**		➔ **CONTINUE**
5. **Always**		➔ **CONTINUE**
20% LOW HEALTH LITERACY QUOTA: **Include at least 1 participant with plaque psoriasis and at least 1 participant with type 2 diabetes who have <u>a score of 1 or 2 on question 18 (i.e., HS or less)</u> OR <u>a score of 3 or higher on question 19</u>**		

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

You have completed the online screener. One of our recruiters will be in touch if you qualify for this study. Thank you for your time.

TELEPHONE ELIGIBILITY AND SCHEDULING CONFIRMATION SCRIPT

[NOTE: THIS SCRIPT WILL ONLY BE USED FOR INDIVIDUALS WHO COMPLETE THE WEB SCREENER

Hello, this is **{NAME}** calling from Schlesinger. I'm calling regarding the online interview study about prescription drug ads you recently expressed interest in.

I'm calling to confirm a few pieces of information you shared with us to ensure you are eligible. If you are, I would like to schedule you to participate in one of the online video interviews. As a reminder, each interview will last about one hour, and we will audio and video record the discussion. You will receive a token of appreciation valued at $50 if you complete the study.

May I ask you a few questions now to confirm your eligibility and schedule your participation?

Yes		➔ CONTINUE
No		➔ **Would another time be better?** **SCHEDULE A TIME TO CALL BACK OR THANK THEM FOR THEIR TIME**

1. Is it correct that you consent to having your interview audio and video recorded, and livestreamed?

Yes		➔ CONTINUE
No		➔ **TERMINATE; SHOW INELIGIBLE CLOSING SCRIPT**

2. Have you ever been diagnosed by a health care provider with either of the following conditions? (Select all that apply).

Plaque psoriasis		➔ CONTINUE
Type 2 Diabetes		➔ CONTINUE
IF <u>NEITHER </u>DIABETES NOR PSORIASIS SELECTED ➔ TERMINATE; GO TO INELIGIBLE CLOSING SCRIPT **SCREEN FOR 50:50 MIX** **If <u>BOTH</u> DIABETES AND PSORIASIS ARE SELECTED, RECRUIT FOR PSORIASIS INTERVIEW IF PSORIASIS RECRUITMENT IS STILL OPEN**		

3. Is it correct that you have access to a reliable, high-speed Internet connection (i.e., DSL or broadband) at the location you will be joining the interview from?

Yes		➔ CONTINUE
No		➔ TERMINATE; GO TO INELIGIBLE CLOSING SCRIPT

4. Is it correct that you have a desktop or laptop computer with a webcam that you can use during the video interview?

Yes		➔ CONTINUE
No		➔ TERMINATE; GO TO INELIGIBLE CLOSING SCRIPT

Thank you for answering all my questions. Based on your responses, we would like to invite you to take part in the study. The interviews will take place on **{DATES AND TIMES}**. Which date and time would work best for you?

Great, we have you scheduled for an interview on **{DATE/TIME}**. I will be sending you a confirmation email with this date and time that will include instructions for accessing the interview and additional information about the study.

I will also email you a day or two before your scheduled appointment to remind you. If you need to reschedule or cancel your appointment, please contact me at **{PHONE/EMAIL}**.

CONFIRMATION EMAIL TO ELIGIBLE RESPONDENTS

Any text in curly brackets "{ }" indicates part of the script that will change based on the participant, or situation. The intended content (or content options) is indicated in the brackets.

Subject: Online Video Interview for FDA Study on Selecting Medical Treatment

Dear **{PARTICIPANT FIRST NAME}**:

Thank you for agreeing to join an interview with RTI International about factors people consider when selecting medical treatments. Your online, video interview is scheduled for **{DAY, DATE}** at **{START TIME – END TIME}{TIME ZONE}.** The interview will take place online and **will last about 60 minutes**. Please be sure to set aside enough time in your schedule for the entire session.

Detailed in this email are some general instructions, followed by specific information needed to participate in the interview.

REVIEWING THE INFORMED CONSENT FORM

Attached to this email you will find the study's informed consent. ***Please read the form carefully before the interview.***

TESTING THE PLATFORM

We will use a video platform called Zoom for the interview and you will need a computer (not just a smartphone) with a web camera to participate.

To make sure that you can join the interview, please test your device and web camera at least 24 hours before your scheduled interview. You can test your equipment by clicking on the test link below or copying/pasting the URL into your web browser.

Zoom Test Link

{INSERT ZOOM TEST URL}

JOINING THE INTERVIEW

Please use the login information below to join the online interview at your scheduled date and time:

1. Click the meeting link:

   {INSERT ZOOM MEETING URL}

2. A pop-up box will appear on your screen requesting to download and run Zoom.

   a. If you would like to install the Zoom app (*the easiest option and the smoothest experience but not required*), click on the file and install the launcher.

   b. If you do not want to install the application, click the "join from your browser" link.

3. For audio, you can use either your computer or a phone. After you login into Zoom using the link provided, you will be able to choose an audio option—computer or phone. If you choose phone audio, please select the option that allows the system to call you (vs. you calling into Zoom). This will suppress your phone number and protect your privacy.

4. Activate your video by clicking the "Start Video" button in the lower left corner of the app.

PROTECTING YOUR PRIVACY

It is important to us that your privacy is protected. We will never ask for your last name or contact information. To help us protect your privacy, please follow these suggestions:

1. **Use Only Your First Name**. When you join the Zoom meeting, you will be asked to sign in or enter your name. Using only your first name allows us to identify you while still protecting your privacy.
2. **If You Join by Phone, Have the System Call You.** This will suppress your telephone number and keep your contact information private.

HELPFUL HINTS

To make the most of the interview, please follow these helpful hints:

1. **Login to Your Zoom Session at Least 5 Minutes before the Interview is Scheduled to Start.** This allows you to test your login information and ensure that the interview begins and ends on time.

2. **Minimize Distractions.** You will need to be seated at your computer with a webcam to participate. Please choose a quiet room where you can participate in private and without any distractions. Alert others in advance that you're giving your full attention to the discussion. Turn off your cell phone, television, and anything else that might distract you. Increase the volume on your device for the best audio quality.

PERSONS TO CONTACT

If you need to reschedule or cancel your appointment, please contact me at **{PHONE/EMAIL}**.

Please keep this information accessible for your interview. Thank you again for your interest. We look forward to seeing you online soon!

{RECRUITER SIGNATURE}

{SIGNATURE LINE WITH PHONE NUMBER AND EMAIL}

Cognitive Interview Reminder Call and No-Show Call Scripts

Any text in angle brackets "{ }" indicates part of the script that will change based on the participant, or situation. The intended content (or content options) is indicated in the brackets.

Reminder Email

Hello **{NAME}**,

Just a friendly reminder that your interview for a research study about the factors people consider when selecting treatments for certain medical conditions is on **{DATE/TIME}**.

Please confirm that you are still able to participate in the interview on {DATE/TIME} by replying to this email.

If you need to cancel or reschedule this appointment, please call our office as soon as possible at **{PHONE}**.

Thank you for your time.

No-Show Call Script

[If participant has not called in for the interview 5 minutes after the start time, the interviewer will alert the Schlesinger Project Manager who will call the participant. The participant will be considered a no-show if they do not show up by 10 minutes past the start time.]

Hello this is **{NAME}** calling from Schlesinger Group regarding the research study you recently agreed to participate in assessing how people select medical treatments. We had you scheduled for an interview today at **{TIME}**.

Are you still able to complete the interview now?

IF NO – Well, thank you for your time.

IF YES – Do you have the confirmation email that includes the instructions for accessing the interview?

> **IF YES** – Great, I will let the interviewer know you will be joining shortly. Thank you for your time.

> **IF NO** – I am resending the confirmation email now. I can stay on the line until you confirm that you have received it. **[ONCE PARTICIPANT CONFIRMS]** Great, I will let the interviewer know you will be joining shortly. Thank you for your time.