OMB Control No. 0910-0695 Expiration date: 3/31/2024

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 0910-0695 and the expiration date is 3/31/2024. 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.

# Appendix A: One-on-One Interview Recruitment and Screener Scripts

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.

#### **DIAGNOSED CONSUMERS**

#### **Email Screener**

## Subject: Interview for FDA Study on Selecting Medical Treatments

Hello, we are currently recruiting consumers for an upcoming research study sponsored by the Food and Drug Administration. The purpose of the study is to understand how people make decisions about medical treatment.

RTI International, an independent, non-profit research institute, will be conducting one-on-one online video interviews on this topic with consumers nationwide. The interview will take up to 60 minutes. Interviews will be scheduled between **{DATE and DATE}**. You will receive a **{\$50 | \$75}** gift card from your choice of a variety of top brands as a token of appreciation. To see if you are eligible, please complete the brief survey linked below. 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: Subset of the Screener Questions Below}**

Thank you for your time. Someone from L&E Research may contact you in a couple of days to finish the screening process if it looks like you will qualify for the study.

#### {Recruiter's name}

{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 L&E Research and I recently sent an email inviting you to participate in an interview. As a reminder, we are conducting online video interviews about how people select medical treatments.

Your input is important, and your participation is greatly appreciated. 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: Subset of the Screener Questions Below}

Kind regards,

**{RECRUITER'S NAME}** 

{Signature line with phone number and email}

#### **Introduction: Telephone Screener**

Hello, my name is \_\_\_\_\_\_, and I'm calling from L&E Research on behalf of RTI International, a non-profit research organization working with the U.S. Food and Drug Administration on a research study. We are conducting online video interviews to learn more about the factors people consider when selecting medical treatments.

L&E Research is currently recruiting participants nationwide for this research study. The interview will last about one hour and will take place on **{DATES}**. As a token of appreciation for taking part in this study, you will receive your choice of a variety of rewards from top brands, either a prepaid e-gift card or a physical gift card equivalent to **{\$50** | **\$75}**.

Before we continue, I want to let you know that the interviews will be conducted through online video conferencing and other members of the study team may observe. The interview will be audio recorded and transcribed. All recordings and transcript files will be kept on password protected computers at RTI and FDA and will only be accessible to study staff.

To protect your privacy, we ask that you only use your first name during the interview, and that you do not disclose personal information about yourself. Your name will not be

associated with the recordings or transcript of your interview, and no one at FDA will have your full name or contact information. RTI project staff will have your phone number so that they can contact you if needed about your appointment. They will delete the records containing this information after your interview has been completed.

To see if you are eligible, I'd like to ask you some questions.

May I continue?

#### Yes **→ CONTINUE**

No → [Thank respondent and end call.]

# **CONSENT TO RECORDING AND LIVESTREAM**

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

Yes	→ CONTINUE
No	→ TERMINATE

2. Do you consent to having your interview livestreamed?

Yes	→ CONTINUE
No	→ TERMINATE

## **CORE ELIGIBILITY CRITERIA**

3. What is your current age?

	 → IF Q1 < 18, TERMINATE
I	

4. Do you read and speak English fluently?

Yes	→ CONTINUE
No	→ TERMINATE

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

Medical Doctor	→ TERMINATE
Any Other Type of Health Care Provider (Nurse, Physician Assistant)	→ TERMINATE
None of the above	→ CONTINUE

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

Allergies	<b>→ TERMINATE</b> (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)	
Psoriasis	→ CONTINUE	
Type 2 Diabetes	→ CONTINUE	
IF <u>NEITHER</u> DIABETES NOR PSORIASIS SELECTED → TERMINATE		
SCREEN FOR 50:50 MIX		

7. Are you currently receiving treatment for {TYPE 2 DIABETES/PSORIASIS}?
FOR TYPE 2 DIABETES: Treatment may include insulin or another medication.
FOR PSORIASIS: Treatment may include a medication or a cream or ointment.

Yes	→ CONTINUE
No	→ CONTINUE

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

US Department of Health and Human Services	→ TERMINATE
Pharmaceutical Company	→ TERMINATE
Market Research Firm	→ TERMINATE
RTI International	→ TERMINATE
None of the above	→ CONTINUE

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

Yes	→ TERMINATE
No	→ CONTINUE

# **TECHNOLOGY QUESTIONS**

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>.

10. 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

11. 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

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

Yes		→ CONTINUE
-----	--	------------

No	→ TERMINATE

# **DEMOGRAPHIC QUESTIONS**

# 13. What is your gender?

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

# 14. 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
Prefer not to answer	→ CONTINUE
SCREEN FOR A MIX	

# 15. Are you Hispanic/Latino?

Yes	→ CONTINUE
No	→ CONTINUE
SCREEN FOR A MIX	

16. 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

#### **HEALTH LITERACY QUESTION**

17. 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 7 participants with psoriasis and at least 7 participants with type 2 diabetes who have a score of 3 or higher

#### INTERVIEW INVITATION FOR ELIGIBLE PARTIPANTS

Thank you for answering all my questions. Based on your responses, we would like to invite you to take part in the study.

If you agree to participate, we can schedule your online video interview now. Each interview will last about one hour, and we will audio record the discussion. You will receive a **{\$50** | **\$75}** gift card from your choice of a variety of top brands after completing the discussion as a token of appreciation for your participation. May I schedule you?

# Yes → CONTINUE to scheduling.

# No → [Thank you for your interest.]

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. I will also be sending 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. I will also call 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}**.

#### **CLOSING FOR INELIGIBLE PARTICIPANTS**

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.

#### **PHYSICIANS**

#### **Email Screener**

## **Subject: Interview for FDA Study on Selecting Medical Treatments**

Hello, we are currently recruiting physicians for an upcoming research study sponsored by the Food and Drug Administration. The purpose of the study is to understand how physicians make treatment decisions.

RTI International, an independent, non-profit research institute, will be conducting one-on-one online video interviews on this topic with physicians nationwide. The interview will take up to 60 minutes. Interviews will be scheduled between **{DATE and DATE}**. You will receive a \$200 gift card from your choice of a variety of top brands as a token of appreciation. To see if you are eligible, please complete the brief survey linked below. If you have any questions about the study, or prefer to complete the screening by phone, I can be reached at **{EMAIL/PHONE}**.

{Survey Link: Survey will include a subset of the screener questions below}

Thank you for your time. Someone from L&E Research may contact you in a couple of days to finish the screening process if it looks like you will qualify for the study.

{Recruiter's name}

**{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 L&E Research and I recently sent an email inviting you to participate in an interview. As a reminder, we are conducting online video interviews about how physicians make treatment decisions.

Your input is important, and your participation is greatly appreciated. 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: Subset of the Screener Questions Below}** 

Kind regards,

#### **{RECRUITER'S NAME}**

## **{Signature line with phone number and email}**

|--|

Hello, my name is	, and I'm calling from L&E Research on behalf of RTI
International. We are conducting	online video interviews to learn more about how physicians
make treatment decisions.	

L&E Research is currently recruiting participants nationwide for this research study. The interview will last about one hour and will take place on **{DATES}**. As a token of appreciation for taking part in this study, you will receive your choice of a variety of rewards from top brands, either a prepaid e-gift card or a physical gift card equivalent to \$200.

Before we continue, I want to let you know that the interviews will be conducted through online video conferencing and other members of the study team may observe. The interview will be audio recorded and transcribed. All recordings and transcript files will be kept on password protected computers at RTI and FDA and will only be accessible to study staff.

To protect your privacy, we ask that you only use your first name during the interview, and that you do not disclose personal information about yourself. Your name will not be associated with the recordings or transcript of your interview, and no one at FDA will have your full name or contact information. RTI project staff will have your phone number so that they can contact you if needed about your appointment. They will delete the records containing this information after your interview has been completed.

To see if you are eligible, I'd like to ask you some questions.

May I continue?

Yes **→ CONTINUE** 

No → [Thank respondent and end call.]

# CONSENT TO RECORDING AND LIVESTREAMING

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

Yes	→ CONTINUE
No	→ TERMINATE

2. Do you consent to having your interview livestreamed?

Yes	→ CONTINUE
No	→ TERMINATE

# CORE ELIGIBILITY CRITERIA AND MEDICAL PRACTICE BACKGROUND

3. Are you a...?

Primary Care Physician (Family Practice, Internal Medicine, General Practitioner)	→ CONTINUE (GO TO Q5)
Specialist Physician	→ CONTINUE (GO TO Q4)
Any Other Type of Health Care Provider (Nurse, Physician Assistant)	→ TERMINATE
None of the above	→ TERMINATE

 4. {IF SPECIALIST PHYSICIAN SELECTED FOR Q3} What is your <u>primary</u> area of specialization (e.g., Internal Medicine, Gastroenterology, etc.)?
 {OPEN ENDED}

5. Are you currently practicing medicine?

Yes	→ CONTINUE
No	→ TERMINATE

6. What percentage of your time do you spend providing direct patient care? Your best estimate is fine.

50% or higher	→ CONTINUE
Less than 50%	→ TERMINATE

7. Which of the following conditions do you treat? (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)	
Hypertension	→ TERMINATE (if Type 2 Diabetes or	
	Psoriasis not selected)	
Psoriasis	→ CONTINUE	
Type 2 Diabetes	→ CONTINUE	
IF <u>NEITHER</u> DIABETES NOR PSORIASIS SELECTED → TERMINATE		
IF <u>BOTH</u> DIABETES AND PSORIASIS SELECTED → CONTINUE TO Q7		
IF <u>ONLY</u> ONE OF DIABETES OR PSORIASIS SELECTED → CONTINUE TO Q8 OR Q9		

8. **{IF BOTH DIABETES AND PSORIASIS SELECTED FOR Q7}** You mentioned you treat both type 2 diabetes and psoriasis. Between these two conditions, which would you say you treat more often?

Type 2 Diabetes	→ CONTINUE
Psoriasis	→ CONTINUE
SCREEN FOR 50:50 SPLIT of most frequently	f Diabetes or Psoriasis as condition treated

9. **{IF DIABETES SELECTED FOR Q7}** In a typical week, how many prescriptions do you write for type 2 diabetes treatments? Your best estimate is fine.

 → CONTINUE

10. **(IF PSORIASIS SELECTED FOR Q7)** In a typical week, how many prescriptions do you write for psoriasis treatments? Your best estimate is fine.

→ CONTINUE
------------

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

US Department of Health and Human	→ TERMINATE
Services	
Pharmaceutical Company	→ TERMINATE
Market Research Firm	→ TERMINATE
RTI International	→ TERMINATE
None of the above	→ CONTINUE

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

Yes	→ TERMINATE
No	→ CONTINUE

# **TECHNOLOGY QUESTIONS**

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>.

13. 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

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

Mac laptop or desktop	→ CONTINUE
Tablet or mobile device	→ TERMINATE

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

Yes	→ CONTINUE
No	→ TERMINATE

# **DEMOGRAPHIC QUESTIONS**

16. What is your gender?

Male	→ CONTINUE
Female	→ CONTINUE
Prefer not to answer	→ CONTINUE
GENDER IDENTITY SOFT QUOTA (~60% MALE/~40% FEMALE):	
Aim to include about 20 male participants and about 15 female	

Aim to include about 20 male participants and about 15 female participants; screen for a mix by gender who treat psoriasis and type 2 diabetes.

# 17. 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
Prefer not to answer	→ CONTINUE
SCREEN FOR A MIX	

# 18. Are you Hispanic/Latino?

Yes	→ CONTINUE
No	→ CONTINUE
SCREEN FOR A MIX	

#### 19. In what state(s) are you currently practicing?

	→ 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

# 20. How long have you been practicing medicine?

Less than 5 years	→ CONTINUE
6-10 years	→ CONTINUE
11-20 years	→ CONTINUE
21-30 years	→ CONTINUE
31 or more years	→ CONTINUE
SCREEN FOR A MIX	

#### 21. How would you classify your practice?

Solo	→ CONTINUE
Small group practice (2- 10 HCPs)	→ CONTINUE
Large group practice (>10 HCPs)	→ CONTINUE
SCREEN FOR A MIX	

#### 22. Do you practice at an academic or teaching hospital?

Yes	→ CONTINUE
No	→ CONTINUE

#### INTERVIEW INVITATION FOR ELIGIBLE PARTICIPANT

Thank you for answering all my questions. Based on your responses, we would like to invite you to take part in the study.

If you agree to participate, we can schedule your online video interview now. Each interview will last about one hour, and we will audio record the discussion. You will receive a \$200 gift card from your choice of a variety of top brands after completing the discussion as a token of appreciation for your participation. May I schedule you?

#### Yes → CONTINUE to scheduling.

## No → [Thank you for your interest.]

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. I will also be sending 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. I will also call 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}**.

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