

Appendix C
Consent Forms

Cognitive Interview Consent Form

OMB Control No. 0910-NEW

Expiration date: xx/xx/xxxx

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-NEW and the expiration date is xx/xx/xxxx. The time required to complete this information collection is estimated to average 60 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

Thank you for agreeing to participate in our research study to learn more about the factors people consider when selecting medical treatments.

Introduction and Purpose:

You have been invited to take part in a research study. The purpose of the study is to get opinions about a survey being developed to understand how people make treatment decisions for certain medical conditions. RTI International, a non-profit research organization in North Carolina, is conducting these interviews on behalf of the US Food and Drug Administration (FDA) who is sponsoring this research.

Procedures:

You are one of approximately 9 people being asked to participate in this study based on your answers to our screening questions. If you agree to participate, you will take part in an online video interview. The interview will take **up to 60 minutes** to complete.

During the interview, you will be asked to take an online survey and share your thoughts about it with an interviewer. The survey will include background questions about your medical condition and factors you consider when choosing a treatment.

Benefits:

There is no direct benefit to you for being in this interview. However, your answers are very important because they will help us improve a survey to understand how patients make treatment decisions.

Risks:

There are no known risks to participating in this study. You will be asked to share your attitudes and opinions; however, the topic is not sensitive in nature. Although the questions we ask are not meant to be sensitive, there is always a chance that you may feel

uncomfortable with some of the questions. Your participation is voluntary, and you do not have to answer any question that you don't want to answer.

Confidentiality:

All information you share in this study will be kept secure to the extent permitted by law. The study team will not disclose your name or any of your responses, and your personal information (name, address, phone number) will not be linked to any of your responses. The information you share with us will be combined into a summary report so that details of individual interviews cannot be linked to a specific participant.

With your permission, the interviews will be audio and video recorded, and the screen with the survey will be livestreamed (a video of your face will be visible in the live-streamed video). We will use the recordings of all the interviews to prepare a summary report; however, we will not connect your name to your responses in any reports. The recordings will be stored on password-protected computers and at the completion of this study, the recordings will be destroyed.

Future Contacts:

You will not be contacted in the future about this study after your participation in this interview ends.

Observation:

Some members of the research team will observe the discussion so they can hear your opinions directly from you. You will not see them on video, but you might see them listed as observers.

Incentive:

Within 2-3 business days of the completion of the study, you will receive a token of appreciation valued at \$50 from Schlesinger Group.

Right to Refuse or Withdraw:

Your participation in this study is voluntary. You can choose not to talk about any topic, and you can withdraw from it for any reason at any time without penalty.

Circumstances Under Which Your Participation May Be Terminated:

Your participation will be terminated if you decide you do not want your interview to be livestreamed or audio and video recorded. If your participation is terminated for these reasons, you will not receive the \$50 token of appreciation. These conditions of participation were explained to you during screening, at which time you agreed for the interview to be livestreamed and recorded.

Persons to Contact:

If you have questions about the study, you can call the project director, Ryan Paquin, at 1-800-334-8571, ext. 22041. He can be reached between 9:00 AM and 5:00 PM Central Time Monday to Friday.

If you have any questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

Please keep a copy of this document for your records.

Research Participant Statement:

I understand what the study involves, and my questions so far have been answered. I understand that my participation in this research study is voluntary. I agree to take part in this one-on-one interview study.

Pretest/Main Study Consent Forms: Diagnosed Consumers

[PROGRAMMER: Some questions have conditional piping in item stems or response options that will depend on the study cohort, as captured in the **COHORT** variable (defined above). The conditional text appears in curly brackets “{ }” with the following rules:

Conditional text	COHORT	Display
{plaque psoriasis \ type 2 diabetes}	1 'Psoriasis'	plaque psoriasis
	2 'Diabetes'	type 2 diabetes
{\ <u>other than insulin</u> }	1 'Psoriasis'	
	2 'Diabetes'	<u>other than insulin</u>
{for plaque psoriasis \ <u>other than insulin</u> for type 2 diabetes}	1 'Psoriasis'	for plaque psoriasis
	2 'Diabetes'	<u>other than insulin</u> for type 2 diabetes
{four \ five}	1 'Psoriasis'	four
	2 'Diabetes'	five
{\$5.00 \ \$4.00}	1 'Psoriasis'	\$5.00
	2 'Diabetes'	\$4.00

Example: For the bracketed text {plaque psoriasis \ type 2 diabetes}, IF COHORT= 1 'Psoriasis', then display “plaque psoriasis” in place of the bracketed text.

[-----New screen-----]
[Consent Screen 1]

What is the Research About?

Thank you for your interest in this research study. The survey will take about **20 minutes** to complete. The survey will include:

- A few questions asking for information about your experience with {plaque psoriasis \ type 2 diabetes}.
- A section which explains {four \ five} factors that you might consider when choosing a prescription drug to treat your {plaque psoriasis \ type 2 diabetes}.

- A series of questions that will ask you to pick which of two prescription drugs you like better, based on the {four \ five} different factors described in the first section.
- Questions that ask you to use numbers to solve a problem.

What is the Purpose of This Study?

The purpose of the study is to better understand how features of prescription drug products impact people's treatment choices. You are one of about 1840 people in the United States who are being asked to complete this study.

Who is Leading the Study?

RTI International, an independent nonprofit research organization, is conducting this study on behalf of, and funded by, a federal agency. RTI is working with Dynata to conduct this survey but is not affiliated with Dynata in any way.

Do I Have to Take Part in this Study?

Your participation in this study is completely voluntary, and you have the right to stop at any time or to skip any question that you do not want to answer. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

What Are the Possible Risks?

There are no known risks to participating in this study. We do not expect that any of the survey questions will make you feel uncomfortable, but if they do, you do not have to answer any question that you don't want to answer. With any online survey, there is a potential risk of loss of confidentiality. Every effort will be made to protect your information, but this cannot be guaranteed.

Will I Benefit from Taking Part in This Study?

There are no direct benefits to you for participating in this study. However, you will be helping with an important research project.

Will I Receive an Incentive for Taking Part in this Study?

You will receive {\$5.00 \ \$4.00} in points as a token of appreciation for completing this survey.

Who Will See the Information I Give?

Many precautions have been taken to protect your information. All information collected in this survey will be kept confidential to the extent provided by law. You will never be identified by name. The study team will not disclose your name or any of your responses, and your personal information (name, address, phone number) will not be linked to any of your responses. When we analyze the results, your responses will be combined with

responses from other people taking part in the study. Details of individual responses will not be linked to a specific participant in any published or presented reports.

Will I Be Contacted in the Future about This Study?

You will not be contacted in the future about this research after your participation ends.

What If I Have Questions?

If you have questions about this survey, please contact your panel provider through your member website for assistance. You will need to mention the Project # **[INSERT DYNATA SURVEY NUMBER]**, and someone will direct your questions to the appropriate researchers at RTI. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

[-----New screen-----]

[Consent Screen 2]

[RADIO; SINGLE PUNCH]

CONSENT. If you have read the previous screens and agree to participate, please click 'Yes'. If not, click 'No'.

- 1 Yes, I agree to participate ← [Must select 1 'Yes' to continue]
- 2 No, I do not agree to participate

[Programmer:

- **If Consent = 1 'Yes', GO TO Section A**
- **If (Consent = 2 'No' or Consent = Null), GO TO REFUSAL SCREEN and terminate survey]**

[-----New screen-----]

[REFUSAL SCREEN]

Thank you for taking the time to answer our questions today.

[IF (CONSENT = 2 'No...' OR CONSENT = NULL), END HERE]

Pretest/Main Study Consent Forms: Physicians

[PROGRAMMER: Some questions have conditional piping in item stems or response options that will depend on the study cohort, as captured in the **COHORT** variable (defined above). The conditional text appears in curly brackets “{ }” with the following rules:

Conditional text	COHORT	Display
{plaque psoriasis \ type 2 diabetes}	1 'Psoriasis'	plaque psoriasis
	2 'Diabetes'	type 2 diabetes
{four \ five}	1 'Psoriasis'	four
	2 'Diabetes'	five

Example: For the bracketed text {plaque psoriasis \ type 2 diabetes}, IF COHORT= 1 'Psoriasis', then display “plaque psoriasis” in place of the bracketed text.

[-----New screen-----]
[Consent Screen 1]

What is the Research About?

Thank you for your interest in this research study. The survey will take about **20 minutes** to complete. The survey will include:

- A few questions asking for information about your medical practice.
- A section which explains {four \ five} factors that you might consider when prescribing a {plaque psoriasis \ type 2 diabetes} medication to your patients.
- A series of questions that will ask you to pick which of two prescription drugs you like better, based on the {four \ five} different factors described in the first section.
- Questions that ask you to use numbers to solve a problem.

What is the Purpose of This Study?

The purpose of the study is to better understand how features of prescription drug products impact people’s treatment choices. You are one of about 1840 people in the United States who are being asked to complete this study.

Who is Leading the Study?

RTI International, an independent nonprofit research organization, is conducting this study on behalf of, and funded by, a federal agency. RTI is working with Dynata to conduct this survey but is not affiliated with Dynata in any way.

Do I Have to Take Part in this Study?

Your participation in this study is completely voluntary, and you have the right to stop at any time or to skip any question that you do not want to answer. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

What Are the Possible Risks?

There are no known risks to participating in this study. We do not expect that any of the survey questions will make you feel uncomfortable, but if they do, you do not have to answer any question that you don't want to answer. With any online survey, there is a potential risk of loss of confidentiality. Every effort will be made to protect your information, but this cannot be guaranteed.

Will I Benefit from Taking Part in This Study?

There are no direct benefits to you for participating in this study. However, you will be helping with an important research project.

Will I Receive an Incentive for Taking Part in this Study?

You will receive a \$45 honorarium for completing this survey.

Who Will See the Information I Give?

Many precautions have been taken to protect your information. All information collected in this survey will be kept confidential to the extent provided by law. You will never be identified by name. The study team will not disclose your name or any of your responses, and your personal information (name, address, phone number) will not be linked to any of your responses. When we analyze the results, your responses will be combined with responses from other people taking part in the study. Details of individual responses will not be linked to a specific participant in any published or presented reports.

Will I Be Contacted in the Future about This Study?

You will not be contacted in the future about this research after your participation ends.

What If I Have Questions?

If you have questions about this survey, please contact your panel provider through your member website for assistance. You will need to mention the Project # **[INSERT DYNATA SURVEY NUMBER]**, and someone will direct your questions to the appropriate researchers

at RTI. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

[-----New screen-----]

[Consent Screen 2]

[RADIO; SINGLE PUNCH]

CONSENT. If you have read the previous screens and agree to participate, please click 'Yes'. If not, click 'No'.

- 1 Yes, I agree to participate ← [Must select 1 'Yes' to continue]
- 2 No, I do not agree to participate

[Programmer:

- **If Consent = 1 'Yes', GO TO Section A**
- **If (Consent = 2 'No' or Consent = Null), GO TO REFUSAL SCREEN and terminate survey]**

[-----New screen-----]

[REFUSAL SCREEN]

Thank you for taking the time to answer our questions today.

[IF (CONSENT = 2 'No...' OR CONSENT = NULL), END HERE]