

Appendix C: One-on-One Interview Consent Forms

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

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 learn more about the factors people consider when selecting treatments 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 70 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, we will ask you about your medical condition, treatment history, and the factors you consider when selecting a new 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 understand how patients make treatment decisions.

Risks:

There are no known risks to participating in this study. 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. 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 recorded but we will not connect your name to the recordings. These recordings will be stored on password-protected computers.

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 thank-you letter from L&E and an email from rewards@tremendous.com explaining how to access and choose your reward. You will receive either a prepaid e-gift card or a physical gift card equivalent to **{\$50 | \$75}** from your choice of a variety of top brands as a token of appreciation.

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 recorded or livestreamed. If your participation is terminated for these reasons, you will not receive the **{\$50 | \$75}** gift card. This condition of participation was explained to you during screening at which time you agreed for the interview to be livestreamed and audio 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.

PHYSICIANS

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

Introduction and Purpose:

You have been invited to take part in a research study. The purpose of the study is to learn more about the factors physicians consider when making treatment decisions for patients. 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 35 physicians 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, we will ask you about your medical practice, your treatment decisions, and the medication attributes you consider when recommending a treatment to patients with certain medical conditions.

Benefits:

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

Risks:

There are no known risks to participating in this study. 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. 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 recorded, but we will not connect your name to the recordings. These recordings will be stored on password-protected computers.

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 our 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 thank-you letter from L&E and an email from rewards@tremendous.com explaining how to access and choose your reward. You will receive either a prepaid e-gift card or a physical gift card equivalent to \$200 from your choice of a variety of top brands as a token of appreciation.

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 audio recorded or livestreamed. If your participation is terminated for these reasons, you will not receive the \$200 gift card. This condition of participation was explained to you during screening at which time you agreed for the interview to be livestreamed and audio 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.

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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.