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 time required to complete this information collection is estimated to average 10 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 [PRAStaff@fda.hhs.gov.](mailto:PRAStaff@fda.hhs.gov)

One-on-One Interview Consent Form

*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.*

Thank you for agreeing to participate in our research study to understand how consumers interpret and react to prescription drug promotions on social media.

**Introduction and Purpose:**

You have been invited to take part in a research study. The purpose of the study is to understand how consumers learn about and interpret information about prescription drugs on social media. RTI International, a non-profit research organization in North Carolina, is conducting these interviews on behalf of the U.S. Food and Drug Administration (FDA) who is sponsoring this research.

**Procedures:**

You are one of 54 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 in-person interview. The interview will take **up to 60 minutes** to complete.

During the interview, we may ask you to engage with specific posts about prescription drug promotions on social media, provide your thoughts on the prescription drug information on social media, and ask about where you would look for more information on a prescription drug.

We will provide you a device and a test account to use. You will not be asked to log in to your personal social media account.

**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 consumers perceive prescription drug information on social media.

**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. Some staff from FDA may choose to silently observe and listen in to the interviews in real time and may also ask questions of participants at the conclusion of the interview.

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, but we will not connect your name to the recordings. These recordings will be stored on RTI’s network, which is protected by a password and two-factor authentication. The information collected in this study may be used or shared for future research studies.

**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 and the FDA will observe the interview via livestream so they can hear your opinions directly from you. You will not see these observers on camera. Only those who have been provided the password will be able to enter the Zoom video conference room.

**Incentive:**

Within 2-3 business days of the completion of your interview, you will receive a thank-you letter from L&E Research (a market research firm) and an email from thanks@leresearch.com explaining how to access your reward. You will receive a $75 e-gift card 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 the study for any reason at any time without penalty. If you must leave or are asked to leave for any reason before the conclusion of the interview, you will receive the full payment amount.

**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 $75 e-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, Kristen Giombi, at 1-919-541-7330. She can be reached between 9:00 AM and 5:00 PM Eastern Time Monday to Friday.

Please keep a copy of this document for your records.

**Research Participant Statement:**

At the start of your interview, a staff member will go over this consent form with you and will ask you if you understand what the study involves and if your questions so far have been answered. They will ask if you understand that your participation in this research study is voluntary and whether you agree or do not agree to take part in this study.

By agreeing to participate in this research, you are not giving up any of your legal rights.

You do not need to sign this form. You will give your verbal consent before the interview.

## **Confirmation Email**

Dear **{NAME}:**

Thank you for agreeing to join an interview with RTI International studying how consumers engage with prescription drug information on social media. The in-person interview details are below and will last about one hour.

Date: **{DATE}**

Time: **{TIME}**

Address: **{ADDRESS}**

The research team will provide a device logged into a test **{Facebook/Instagram}** account, so you don’t need to bring your own device if you don’t want to. You will not be asked to log into your personal account.

Before you arrive for your interview, we’d like you to review some important information described below.

**REVIEWING THE INFORMED CONSENT**

Attached to this email you will find the study’s informed consent. ***Please read the form carefully before the interview.*** You do not need to sign it.

**PROTECTING YOUR PRIVACY**

It is important to us that your privacy is protected. We will never ask for your last name or contact information

**PERSONS TO CONTACT**

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

Thank you again for your interest. We look forward to seeing you soon!