AGREEMENT TO PARTICIPATE

SITE SUPERVISOR:	[INSERT LOCATION CONTACT NAME]
INTERVIEW LOCATION:	[INSERT INTERVIEW LOCATION NAME]
MARKET:	[INSERT MARKET LOCATION]

Introduction and Purpose

You have been invited to participate in a communications study. The purpose of the study is to see whether the product label for a medication that may become available without a prescription is easy to understand. Concentrics Research, in collaboration with RTI International, a non-profit research organization in North Carolina, is conducting this study sponsored by the US Food and Drug Administration (FDA). FDA is responsible for approving new drugs and making sure that people understand the drug labels so they can use the product safely and effectively.

This document explains the purpose of the study, what the benefits and risks of participation are to you, and important information about confidentiality. It also says that the research is completely voluntary, which means you can stop or leave the room at any time. Please read this information carefully and ask any questions that you have prior to signing this agreement. The study staff is available to answer your questions.

Confidentiality:

Your participation in this study will be kept confidential by RTI and Concentrics. The information that you give us will be combined with the responses of other participants in a summary report that will not identify you by name. All notes taken during the interview and any forms related to the project that have your name on them will be kept in a locked file cabinet or on a password-protected computer. Only authorized project staff will be able to see them. We will also be audio recording our discussion. The audio files and transcripts will be stored on password-protected computers at RTI and Concentrics.

Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the interviews. RTI, Concentrics, and FDA will maintain the tapes and transcripts securely until they are destroyed at the end of the study. You will not be contacted in the future about this study after your participation in this interview ends. We are conducting these interviews in private settings so that no one outside of the study team will be able to hear what you say.

Privacy of Personally Identifiable (PII) and Protected Health (PHI) Information

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The study staff will be asking you some initial questions about yourself, which could include any or all of the following: your first name, address, phone number, and email address. This information that we are asking you for is called personally identifiable information. These questions are asked so the study leaders know that we had real people answering the study questions. You should know that your identity is protected by assigning you a study number ("subject number") that will identify you throughout the study instead of your name. Your participation in this study will be kept confidential by RTI and Concentrics.Transcripts and audio files with all personally identifiable information removed will be provided to the FDA after the completion of the interviews.

The study staff will also be asking you some initial questions about whether you use certain drugs. This is called protected health (PHI) information. They will also ask whether you have friends or family members who use certain drugs. These questions are being asked to make sure that the people in the study are representative of actual people who might use this product. This is important when we ask whether people understand a label.

Personal health information is protected by a federal law under the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA).

The following people will have access to your personally identifiable information:

- Study staff from Concentrics Research and RTI International (the companies that are managing this study)

The following people will have access to your protected health information:

- Study staff from Concentrics Research and RTI International (the companies that are managing this study
- Study sponsor (FDA) (but without personally identifiable information attached – it will all be anonymous)
- The Institutional Review Board that reviews this study (if applicable)

We will do our best to make sure your information stays private, given the confidentiality procedures that we have described.

You may decide not to sign this authorization (by not signing this consent form). You may take back your authorization at any time by writing to:

Claudia Squire
RTI International
3040 Cornwallis Road
Durham, NC 27709

If you decide not to sign this authorization form, you will not be able to take part in the interview. If you sign this authorization and decide later to take it back, you will be dropped from the study at that time. Data collected up to this time may be used as study data.

At any time, you can tell us to stop using health information that can be traced to you. If you have any questions about this, please ask the study staff. Your permission to use your personal health information will end fifty (50) years from the date you sign this paper.

By signing this document you are agreeing to let us use and share your health information for this study. You will receive a copy of this document.

Study Overview:

Today you will be participating in a study involving an interview about a medication label. You will not have any medical procedures and you will not be given any medication to take. We are interested in getting your insights on the medication's label.

For this specific study, you will be asked to do the following:

- Review labeling about a medication
- Answer some questions about the labeling

Today's interview will be audio recorded. This is for the purpose of taking notes on your feedback so we can understand your responses. Some interviews may also be observed by study staff on-site. We will let participants know when their interviews are being observed. There will be no video recording of the interviews.

Estimated Participation Time:

45 minutes

Estimated Number of Subjects to be Enrolled in the Interview Study:

Approximately 36

Benefits:

There will be no direct benefit to you for participating in this study; however, the information we gather during this study can benefit others by making sure they understand the label on the medication.

Risks:

There are no anticipated risks for your participation in this study since there will not be any medicine taken. The only potential risk is that of privacy or confidentiality. If you are concerned about any risks you can choose not to participate.

Compensation for time and expense:

You will be compensated for your time and expense. The compensation for this interview study will be $XX.00. If you leave the study early you will be paid only for the parts of the study you complete.

Persons to Contact:

If you have questions about the study, you can call Claudia Squire, at (919) 541-6613 between 9:00AM and 5:00PM Eastern Standard Time Monday- Friday.

Voluntary Participation:

Your participation in this interview study is completely voluntary. This means that you can stop or leave at any time.

PARTICIPANT SIGNATURE

_____

Printed Name of Participant

_____

Signature of Participant

_____
Date

STUDY STAFF MEMBER ADMINISTERING THE AGREEMENT

_____
Printed Name of Study Staff Member

_____
Signature of Study Staff Member

_____
Date