

OCP Labeling Project

Alternative Presentations of Clinical Pharmacology in Approved Drug Labeling: Effect on Comprehension, Memory, and Action

Participant Screener

[Note: this section is included within the instrument]

General Background

Please provide some general background information.

Are you: male female

What is your age? _____

What is your occupation?

Physician Physician Assistant Nurse Nurse Practitioner Pharmacist

Other (specify: _____)

What is your highest degree? _____

When did you complete it? Enter year: _____

How long have you been in practice? _____

Where do you work?

State: _____

Type of setting (check all that apply): hospital clinic private practice
 other (specify: _____)

What is your specialty? _____

How would you describe your ethnicity:

White Hispanic African American Asian Other

Is English the first language you spoke?

--If not,

What was the first language you spoke? _____

How old were you when you learned English? _____

Consent Form

Alternative Ways to Display Prescription Drug Information IRB # ____

This study is offered by the Medical Cognition Lab at Duke University, in collaboration with the FDA Office of _____. You will see information about a prescription drug, and then answer some questions about it. Some of the questions are about how the information is displayed and some are about the information itself.

The study takes about 30 minutes. Be sure you have enough time to do this now. Do you have at least 30 minutes now?

Yes No

Research

Benefits of participating in this research:

You may learn about:

- 1) How you understand prescription drug labeling
- 2) How you can improve those skills, to optimize efficiency and accuracy

This research may help us:

- 3) improve how drug information is provided

There are no known risks in participating.

Privacy

Your responses

--will be kept private.

You will be assigned a numerical code by the data collection software. This code is used in data files and statistical analyses. Access to data files is restricted to the research team. Shared electronic files are password protected, while any hardcopy versions are kept in a locked laboratory with access only by the research team.

We will not ask

--for your name or any other information that could identify you.

We will not inform

--your employers or colleagues about your participation.

Reports

Results will be reported in aggregate form. If/when an individual response is presented as an example, no information concerning the identity of the participant will be given

Questions?

If you have any questions

--about participating in this study, please email coglab@duke.edu.

Participate?

Do you agree

--to participate in this research?

Yes No

Recruitment Email

[Note: Permission to contact participants is approved by organizations in advance (e.g., hospitals, professional societies). They may provide email addresses or send out the recruitment email themselves). Below is the basic email sent to prospective participants, with details to be selected and/or filled in for each organization, as indicated in square brackets. Additional information about approval from the organization may also be included, as required by each.]

Dear [Physician, Healthcare Provider, Pharmacist],

You are invited to participate in a brief study on effective ways to present information about prescription drugs. The study is offered by the Medical Cognition Laboratory at Duke University and the FDA Office of _____. You will see some information about a prescription drug and then answer some questions about it. You will also view different ways to display the same information and provide feedback about your preferences.

The study will take about 30 minutes. There is no monetary compensation for your time, but the results will be used to help optimize all drug labeling in the future – to make it easier to find, understand, remember, and use the information. If you would like to participate, please [click here](#) to go to the study site. We will not inform your [worksite, professional organization] about whether you participate or not, nor inform anyone about your responses. Additional information about privacy and security of your responses is provided at the study site.

Thank you for considering this request. We hope you will participate.

Sincerely,

The Effective Labeling Study Team

--Medical Cognition Laboratory, Duke University

--FDA Office of _____