

OCP Labeling Project

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

Consent Form

Alternative Ways to Display Prescription Drug Information IRB #____

This study is offered by the FDA Center for Drug Evaluation and Research's Office of Clinical Pharmacology in collaboration with the Medical Cognition Laboratory at Duke University. 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