

Title of Research Study: The Influence of Brand and Principle Display for Safe Consumer use of Over the Counter Drugs – Advancing the Science

Investigator: Dr. Michael Wolf PhD, MPH

Supported By: The US Food and Drug Administration (FDA)

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are between 18 and 80 years old and may have had interactions with over the counter medicines.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to any of the research team by calling the number (312) 503-3272.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

This study is being done in order to understand how consumers identify and use over-the-counter medications .

How long will the research last?

This research consists of a one in-person interview that will last 45 minutes.

How many people will be studied?

We expect about 400 people will be in this research study.

What happens if I say “Yes, I want to be in this research”?

If you participate in this research you will be asked to participate in an interview with research staff to be completed either now at this location or at a later time at Northwestern University General Internal Medicine offices at 750 N Lake Shore Dr. In this interview you will be asked

about your experience and familiarity with over the counter medications. With your permission, we will audio-record your answers to the questions asked for quality assurance purposes and to supplement our notes. Audio recordings will be saved under a unique study ID on secure Northwestern servers – your name will not be included. These recordings will be destroyed at the end of the study.

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you. You may choose not to participate in this research study.

What happens if I say “Yes”, but I change my mind later?

Your participation is voluntary. You can leave the research at any time and it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove your information and interview responses from the study. We will keep all data collected until the time you change your mind.

Is there any way being in this study could be bad for me?

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. You may also stop participation at any time or skip any question that you feel uncomfortable answering .

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include informing the researchers of how consumers choose over the counter medications .

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution and the FDA.

What else do I need to know?

If you agree to take part in this research study, we will pay you \$30 cash at the end of your interview for your time and effort.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

_____ _____ The researcher may audio record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

_____ _____ The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent