The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT BY SUBJECT FOR PARTICIPATION IN A RESEARCH

Protocol Number: IRB15-1227 Name of Subject: _____
Grant Number: FDA 1U01FD005485

Study: Identifying Messages to PROmote Value & Education (IMPROVE) of Generic Prescribing
Investigators: *Vineet Arora, MD, MAPP; Jeanne Farnan MD, MHPE; David Meltzer MD, PhD; James Zhang PhD, MS; Bradley Shapiro PhD*
Address: 5841 S. Maryland Ave, MC 2007, Chicago, IL 60637
Telephone Number: 773-834-8157

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand the barriers and facilitators to prescribing generic drugs. By using rigorous mixed methods research, the purpose of this study is to uncover the best messages that can promote greater generic prescribing of three routinely used classes of drugs in primary care: antidepressants, oral contraceptives, and cholesterol lowering drugs.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 48 people will take part of this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate, researchers from the University of Chicago will interview you regarding your experiences with generic drug prescribing. These interviews will take about an hour and will be conducted in larger focus groups. Interviews will take no more than an hour to complete. Interviews will take place at ACP/AANP and will be audio-taped at the consent of the participating subjects.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for the duration of the time it takes to complete the focus groups, which we estimate will be about one hour long.

Dr. Arora may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

There is a small risk that information about you or statements made by you during the focus groups could become known to unauthorized persons, but we have safeguards in place to prevent this from happening. If you agree to participate, all information will be kept confidential and in locked files belonging to the researchers. We will not share the information with anyone not working on this study, and we will remind all focus group participants of their obligation to respect the confidentiality of their fellow participants.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study there will not be any immediate benefit to you. However, we hope the information learned from this study will benefit individuals in the future by improving the prescribing of generic drugs.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

1) You may choose not to participate.
2) You may refuse to answer any questions that are asked of you.

Your participation is voluntary, and your decision whether or not you wish to participate in this study will not affect your affiliation with ACP/AANP.

WHAT ARE THE COSTS?

There is no cost involved in participating in this research study.

WILL I BE PAID FOR MY PARTICIPATION?

For participation in this study you will receive a $100 ACP education credit.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Your research consent forms will be kept at the University of Chicago as locked paper files for years after the close of the study. The data gathered will then be stored on a password-protected computer for the duration of the study. All audio recordings will also be stored on a password protected computer if converted to digital form. These recordings will be labeled with a numerical code in place of a name so as to better preserve confidentiality.

The data collected in this study will be used for the purpose described in this form. This data will not be shared with anyone who is not on the research team. The research team includes the individuals listed on this consent form and other personnel and institutions involved in this study. Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to participate at any time during the study.

If you choose to no longer be in the study and you do not want any of your information to be used, you must inform Dr. Arora in writing at the address on the first page. Dr. Arora may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to Dr. Arora about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Vineet Arora at 773-834-8157.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5751 S. Woodlawn Ave., McGiffert Hall, Chicago, Illinois 60637.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____
Date: _____ Time: _____ AM/PM (Circle)