

Statin Treatment Experience Survey Participant Information Sheet

INTRODUCTION:

Please read this information sheet carefully before you make your decision about participating in the research study. If you have any questions or do not understand something in this document, please call the HRA study coordinator toll free at (855) 563-6341.

Your participation in this study is entirely voluntary. If you choose not to participate, or if you stop answering the study questionnaire at any point, there will be no penalty and this decision will not impact your medical or health care in any way.

PURPOSE:

The purpose of this study is to learn about several aspects of patients' experiences with statins. Specifically, this survey will ask you questions about things like:

- your general health history and demographic information,
- any potential side effects or symptoms you've experienced due to statin medications,
- the process of managing statin therapy with your doctor, and
- the overall impact of statins on your everyday life.

It is planned that about 100 people will be in this study.

PROCEDURES:

To participate in this study, you will need to have access to a computer and the Internet. **This web-based survey will take approximately 30 minutes to complete.** Please take the entire survey at a single time. When taking the survey, try to identify a location that will allow you to concentrate on your responses. The survey is best accessed via a desktop, laptop, or tablet. We discourage you from taking the survey on a handheld mobile device, but if you do, you may need to hold the device horizontally for a better view. We recommend using a minimum of Google Chrome Version 27, Internet Explorer Version 10, or Mozilla Firefox Version 20 (or later versions) as the internet browser to complete the questionnaire.

RISKS AND DISCOMFORTS:

This study should not involve any physical risk to you. There is no study medication involved, and you will not receive any medical benefits from participating in this study. Nothing will change about your regular medical care whether or not you participate in this study.

It is possible that some of the questions you will be asked could make you feel uncomfortable. You will be asked to answer questions about private matters that relate to your present state of health and your finances, which could cause you to feel a loss of privacy.

Your participation is voluntary. You may decline to answer any of the questions presented in the questionnaire, and you may choose to stop answering the questionnaire at any time by closing your browser. If you choose to stop answering the questionnaire and leave the study, the researchers will still be able to use and share the information that has already been collected.

Your privacy is protected. HRA will not share your personally identifiable information (such as your address, if you provide it for compensation) with anyone without your permission unless required by law. Your responses to this survey are also confidential. Be aware that your survey responses and other information will be shared as needed for the study. For example, the sponsors and Quorum Review may look at your information. Publications resulting from this research will not individually identify you. You will read more about how your information will be protected later in this form. Please also see HRA's Privacy Policy for additional information.

While all of these study procedures are designed to protect the information you provide and keep your participation confidential, there could be a risk of unintentional loss of confidentiality of your information because it is being provided over the Internet.

CONTACTS:

You can ask questions about the study at any time. You can call the study coordinator at any time if you have any questions, concerns, or complaints about the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks.

If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study coordinator, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

Quorum Review is located in Seattle, Washington.

Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.

Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

ALTERNATIVES:

This study does not involve any treatment for your health condition. Due to the nature of this study, which is limited to answering a questionnaire once via the Internet, your alternative is to not participate.

BENEFITS:

You will not receive any medical benefits from participating in this study. However, your responses may help researchers better understand, and develop ways to improve, the experience of future patients receiving or considering therapy with statin medications.

FINANCIAL ASPECTS:

Compensation

If you are eligible and complete the entire survey you may choose to receive a \$75 gift card. The first few questions will determine if you are eligible to complete the full survey. If you do not meet eligibility, you will be exited from the survey.

Once you have completed the survey, you will be given the opportunity to provide your mailing address to receive the gift card. Your address will **ONLY** be used for the purposes of sending your gift card. If you leave the survey early, or prefer not to provide your mailing address, you will not receive compensation. Only one questionnaire response (and one gift card) per person will be allowed.

Costs

There will be no cost to you to participate in this study.

SPONSOR:

The study is sponsored (paid for) by the National Lipid Association and Amgen Pharmaceuticals, and is conducted by a third party survey company, Health Research Associates, Inc. (HRA), a research organization with experience in health care research.

AGREEMENT TO PARTICIPATE:

After you have read and understood this information about the study and have called the research coordinator to ask any questions you might have had, please decide if you would like to participate. To take part in this study, log on to the questionnaire site, confirm your willingness to participate, and answer the screening questions.

Once you do that, you will see the questionnaire on the screen. When you get to the end of the questionnaire, you have the opportunity to provide a mailing address to receive study compensation.

Thank you for your time and consideration!

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?

This section explains who will use and share your private information if you agree to be in this study. If you do not agree to this use and sharing, you should not participate in the study.

During the study, the study coordinator and other study staff will use, collect, and share information about you (your “study records”). Your study records may include any information about you that the study staff needs to do the study and other identifying information about you, such as your name, address, phone number, or social security number. Your study records will also include:

- your questionnaire responses
- other information collected about you during the research

Your study information will be used or shared when required by law. Your study records may be used and shared with these people for the following purposes:

- The study coordinator and other study staff at your clinic and at Health Research Associates, to conduct the research described in this consent form.
- The sponsors (the National Lipid Association and Amgen Pharmaceuticals); people who work with or for the sponsors; and other researchers involved in this study. These people will use your information to review the study and to check the results of the study.
- Others required by law to review the quality and safety of research, including the U.S. Food and Drug Administration (FDA), other government agencies in the United States and other countries, and Quorum Review.

There are national and state laws that make the study staff protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the study staff share information taken from your records with the sponsors and others, the laws may no longer protect the privacy of your records. The sponsors or others may share the study information that comes from your records with other people who do not have to protect the privacy of your records. If

all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes.

No publication or public presentation about the research described in this information sheet will reveal your identity without permission from you.

You might have the right to see and copy your records related to this research. You might not be able to see or copy some of your records until after all participants finish the study.

You can cancel this authorization to use and share your study records at any time. If you want to cancel your authorization you must do so in writing. If you cancel your authorization, you will not be able to continue in the study.

Even if you cancel your authorization and leave the study early, the study coordinator and study staff will still be able to use and share your records that they have already collected as described above. The authorization to use and share your study records expires in 50 years.