University of California, San Diego
Consent to Act as a Research Subject
UCSD Statin Effects Study

Beatrice A. Golomb, MD, PhD and her colleagues are conducting a research study to find out more about possible side effects (such as muscle pain and fatigue, memory loss, lowered thinking ability, change in mood, tingling or numbness) of cholesterol-lowering drugs (such as Lipitor, Zocor, Pravachol, Mevacor, Lescol, Crestor or other cholesterol-lowering treatments). You have been asked to take part in this study because you have reported that you experienced problems while on statin or other cholesterol-lowering therapy. Roughly 10,000 people will be asked to complete questionnaires.

If you agree to participate in this study, you will be asked to:

1. Fill out one or more questionnaire(s) either in writing or by telephone asking you about your experience taking statins or other cholesterol-lowering treatment. The questionnaire(s) may take up to 45 minutes to complete. They may take less or more time depending on your experience.
    a. If you will be completing the questionnaire by telephone, your conversation may be audio-taped. You will be given a separate consent to agree to the tape-recording. The tape recording will allow us to accurately transcribe the questionnaire on your behalf. At any time, you may decline and the recording may be stopped and/or portions of the entire tape may be erased upon your request. Tapes will be kept in a locked file room, however the tape may be destroyed upon your request at any time.
2. Provide some additional information such as cholesterol levels, current medications and whether you have had heart problems.

If you agree to participate in this study, you might be asked to:

1. Repeat the questionnaires for reliability purposes (20 participants will be asked and will be randomly selected, per month)
2. While the study is ongoing, allow us to request and review your medical records once through the use of a separate HIPAA authorization for cross-checking and validity (100 subjects, randomly selected). We will only be reviewing your history of lipid status (LDL, HDL, triglycerides, total cholesterol, CK levels) and your history of statin use (diagnosis, medical tests, and visits associated with statin use). All information provided by medical records will be abstracted and only identifiable through your assigned unique study number, and records will be stored in a locked file cabinet. Only study staff who have signed confidentiality agreements will have access to your information.

If further clarification of information from your completed questionnaire is needed, a member of our study staff may contact you. Participation in this research is entirely voluntary. You may refuse to participate or withdraw at any time. All questions and items in this questionnaire are completely voluntary, and you may decline to participate or answer any question at any time.

There may not be any direct benefit to you from participation in this study. However, the findings may be of help to future patients on cholesterol drugs. The study may provide valuable

new information about side effects of cholesterol medicines, addressing many of the questions we (the investigators) are often asked by patients. Thus, we may learn more about how serious the effects can be, how often (and how completely) the problems resolve when the drug is stopped, how long it takes for improvement to occur, whether certain cholesterol drugs or doses are more or less likely to cause problems, and whether any treatments are reported to help the problems. This information may help both patients and doctors make the best decisions.

Risks of participation are minimal, and are those risks associated with completing any survey. Loss of confidentiality is a possible risk, but we take pains to limit this risk by assigning each participant a unique study number. All risk of identifying information obtained from reviewed medical records and tape recordings will be minimized; data will be abstracted and only be identifiable through a unique study number and all tapes will be destroyed immediately. Only study personnel who have signed confidentiality agreements and the UCSD Institutional Review Board will have access to any information provided and no identifying information will be published. Research records will be kept in a locked cabinet and confidentiality will be maintained to the extent provided by the law.

If you have any questions, or research-related problems, you may contact the UCSD Statin Study at (858) 558-4950 x201. You may call the University Human Research Protections Program Office at (858) 455-5050 for more information about rights as a research subject or to report research-related problems.

You have either received a copy of the "Notice of Privacy Practices" booklet or given the online address where the contents of this booklet can be found. You have also been given a hard copy or an electronic version of "The Experimental Subject's Bill of Rights" to keep.

Please sign and date below if you agree to participate; and thank you so much for kindly taking the time to share your experience.

_____ _____

Subject's Signature Date

_____ _____

Print Name Date