

The Collaborative Data Project

IRB# 2006-007

Principal Investigator: Elliott Vichinsky, MD

Synopsis:

The purposes of this study are to:

- 1) gather medical information about a large number of patients with sickle cell disease over a period of time;
- 2) plan and identify patients for future studies so that researchers can learn more about the disease;
- 3) gather information about how sickle cell disease affects quality of life; and
- 4) look at the relationship between patient characteristics and medical events.

About 2,300 adults and children with sickle cell disease will take part in this study throughout the United States; about 300 at Children's Hospital and Research Center Oakland will participate.

The study is sponsored by the National Heart, Lung, and Blood Institute (NHLBI), who gives money to a group of research centers that collectively make up the CSCC (which stands for "Comprehensive Sickle Cell Centers") to do research that will find ways to improve the health care of people with sickle cell disease. Rho Federal Systems Inc. is a clinical research organization that helps the NHLBI collect and analyze the research data that come from various research centers, including CHRCCO.

With the subject's consent, Dr. Elliott Vichinsky and the study staff will submit information to a database at Rho, Inc. about subjects' past medical history, physical exams, blood tests, and other medical and demographic information twice a year for at least the next 5 years. This database is a collection of similar information from patients at all of the 10 sickle cell research centers.

There will also be a short interview about the subject's health and lifestyle once a year for the next 5 years. The length of the interview is about 10 minutes. This information will also be stored on a computer at Rho, Inc.

During the next 12 months you will be asked to complete two short questionnaires: a Health-Related Quality of Life form and a Patient Satisfaction form. These questionnaires ask about how you feel about your life, your ability to do things, the health care you receive, and how sickle cell disease has affected you and your every day life. You may be asked to complete these questionnaires one or two more times in the future, to see if there is any change in the way your life has been affected by sickle cell disease.

The information submitted to the database at Rho, Inc. will NOT include the subject's name or any other identifying information.