



August 03, 2001

MR. DANIEL FINNEGAN
4708 W POINT LOMA BLVD 1
SAN DIEGO, CA 92107-1427

Dear MR. FINNEGAN,

If you have already participated in this research study, please disregard this letter and accept my sincerest apology for any inconvenience.

As I mentioned in my brief note at the front of your Health Appraisal questionnaire, I would like your help in a medical research project.

Introduction:

You probably know that iron deficiency can cause anemia. However, *too much* iron can also cause serious health problems such as diabetes, cancer, and liver disease. The most common cause of iron overload is a genetic disorder called Hemochromatosis which occurs in about 1 out of every 250 Americans. The routine way of detecting Hemochromatosis is by a one-time blood test that determines whether or not a person has too much iron in their body. In this research we want to study whether a new genetic test offers a better way of detecting Hemochromatosis.

Hemochromatosis and related diseases of iron overload are important to identify because;

- Early diagnosis and treatment can prevent organ damage from iron overload.
- Early diagnosis can help identify affected family members before they become ill.

Purpose of the research:

In late 1996, a blood test was developed to detect the actual gene causing most cases of iron overload. This study will compare the new genetic test with the routine iron test to determine which test is better to detect Hemochromatosis. I am asking you to participate in this research study that would test your blood by *both* the genetic test and the routine iron test for Hemochromatosis.

Procedures:

If you decide to participate in this research study, there are no medicines to take and no experimental treatments to undergo. However, your permission is needed to perform some extra tests on the blood we collect from you on the day of your Health Appraisal. Nothing else is required. The only genetic testing performed on your blood will be for Hemochromatosis and conditions associated with iron overload.

Confidentiality

The genetic analysis of your blood will be performed at Scripps Research Institute. Only a code number, not your name, will identify your blood sample. No identifiable medical information about you will leave Kaiser Permanente. Your blood sample will be stored at the Scripps Research Institute in case any tests need to be repeated, and to continue to look for other gene alterations that may cause

Hemochromatosis.

If the results of your genetic test indicate that you have a risk of Hemochromatosis, you and your doctor will be informed. These genetic test results will also be entered in your medical record so that your doctors in the future will have this information. The results will be kept in a research file. We will protect your privacy to the limits of the law.

Benefits:

If the genetic test showed that you had Hemochromatosis which had not yet caused damage to your organs, the advantage would be that a preventive treatment to bring iron levels to normal would be provided. This simple treatment consists of removing blood, much like donating blood, and removes excess iron from the body and prevents its damaging effects.

Risks:

It is important to understand that screening for Hemochromatosis using standard chemical tests for iron is now a routine for everyone going through the Health Appraisal Clinic. This research project just adds a genetic test for diagnosis of the same condition.

It is possible that the genetic test may be abnormal in some healthy people who are unlikely ever to become ill from Hemochromatosis. In this case they could be identified as having a genetic disorder without actually becoming ill from Hemochromatosis in their lifetimes.

Just as with being diagnosed with other diseases like diabetes, an abnormal genetic test indicating risk for Hemochromatosis might affect your future life insurance, health insurance, disability insurance, or job prospects. You will never lose your Kaiser Permanente insurance-because of the genetic-test for Hemochromatosis In- addition, we provide a letter to any other insurance company stating that there is no ill effect from Hemochromatosis on health or lifespan when treatment is begun before organs are damaged. However, there is no guarantee that our letter will change the insurance company's decision.

Implications for family members:

How might a diagnosis of Hemochromatosis affect your family? Hemochromatosis is an inherited disease which means that, if you are found to have it, other members of your family might also have it. If you turn out to have iron overload, this information should be shared with your family so they can be tested for Hemochromatosis. Early diagnosis can lead to treatment before serious organ damage occurs. If you decide to tell your family, we will provide you the necessary information for your family members.



Treatment of iron overload:

If you are found to have Hemochromatosis, we will provide you additional information about the disease and its treatment. We will provide genetic counseling to inform you about the implications for you, your relatives, and your children. These are standard services at Kaiser Permanente and will be provided at no cost.

Other considerations:

We will never use your blood to develop a process that will be sold or patented

Your Decision:

This is a voluntary research study., You do not have to .participate and you may withdraw at any time. However, the traditional chemical measurements of iron to detect Hemochromatosis are a routine part of care in the Health Appraisal Clinic. Whether you decide to participate or not in this genetic study of iron overload disease will in no way affect your medical care or your insurance with the Kaiser Health Plan.

Additional option:

I would also like you to consider the additional choice of allowing your blood to be stored for possible use in future research on other diseases like heart disease, abnormal blood clots, diabetes, and cancer. However, if you wish to participate only in the genetic testing portion of the Hemochromatosis Study, you may indicate on the consent form that you do not wish your blood stored for future research on other diseases.

Questions:

If you think you might like to participate, but have questions about this research project you may call Dr. Vincent Felitti's office at (858) 573-5586.

If you are willing to participate, please sign the consent form on the next page and do not take any vitamin or mineral supplements for 24 hours before you come in for your first visit to Health Appraisal. Give the letter of consent to the person drawing your blood at your upcoming visit to Health Appraisal..

Sincerely yours,

Vincent J. Felitti, MD



KAISER
PERMANENTE

MR. DANIEL FINNEGAN

**CONSENT TO PARTICIPATE IN THE NATIONAL INSTITUTE OF HEALTH HEMOCHROMATOSIS
RESEARCH STUDY
SPONSORED BY KAISER PERMANENTE/SCRIPPS RESEARCH INSTITUTE**

I acknowledge

1. No patient identifiable information obtained as a result of participation in this study will be released without patient consent, except possibly to Scripps Research Institute, the National Institute of Health, the Food and Drug Administration, and/or other Federal or State Agencies, which review medical records during the course of their audit responsibilities.
2. My consent to participate in this study may be withdrawn at any time without affecting my future medical care
3. My questions regarding this study have been answered. If I have any additional questions about this study, I may contact:

Vincent Felitti, M.D. (858) 573-5586
4. If I have any additional questions about my rights as a research subject, or in the event of a study related injury, I may contact:

Marsha Price (818) 564-3479
5. In the event complications arise as a result of participation in this study, the physicians and/or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals will render necessary medical care and treatment in accordance with the patient's contract with Kaiser Foundation Health Plan. However, no financial remuneration is available.

I have read the information letter and invitation to participate in the research study entitled: "National Institute of Health Hemochromatosis Study" conducted by the physicians and/or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals. I understand there are two parts of the study:

- Comparing the standard test for hemochromatosis with a new genetic test for hemochromatosis
- An additional option to allow my blood to be stored for possible use in future research on other diseases.

I understand I may consent to one or both parts of the study. My signature indicates I agree to participate in the parts of the study as indicated below.

I agree to allow my blood to be tested comparing the standard test for hemochromatosis with the new genetic test.

I agree to allow my blood to be tested comparing the standard test for hemochromatosis with the new genetic test. In addition, I consent to allow blood to be stored for possible use in future research on other diseases.

DATE: PATIENT: _____

DATE: WITNESS: _____