FRED HUTCHINSON CANCER RESEARCH CENTER/
CENTERS FOR DISEASE CONTROL

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CONSENT TO PARTICIPATE IN

THE HANFORD THYROID DISEASE STUDY

HANFORD THYROID DISEASE STUDY

Fred Hutchinson Cancer Research Center
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Investigators Statement

This is a study about thyroid disease in people who may have been exposed to radioactive iodine released from the Hanford Nuclear Site from 1944-1957. The primary purpose of this study is to find out if some people developed thyroid diseases because of this exposure. In addition, we will also determine if some people may have developed parathyroid disease since this gland lies adjacent to the thyroid gland. We believe the information gathered here will help determine whether living near Hanford from 1944-1957 has resulted in an increased risk of developing thyroid disease.

If you agree to participate, we will ask that you take part in an interview, and to have a thyroid ultrasound scan, a thyroid examination, and a blood sample collected. An explanation of the thyroid ultrasound scan and a request for consent to perform this procedure are in a separate consent form.

The interview will be with a member of the research staff, and will take about 45 minutes. We will ask questions about where you have lived and worked, your smoking habits, dental history, and other questions about your general health. A small number of participants will be recontacted at a later date and asked a few questions to verify that the interview was conducted and all questions were asked.

The thyroid examination will be done by two medical doctors who specialize in thyroid disease. They will feel (palpate) your thyroid gland while you swallow water. It usually takes about 10 to 20 minutes for an exam. The examination is not painful and there are no risks or side effects from it. The results will be explained to you at the clinic after the examination. There is no charge for this examination.

If something abnormal is found during the examination, the doctors will explain to you what they think is wrong, and what they feel you should do next. They may recommend that you have additional tests. The types of additional tests they may want to perform include a fine needle aspiration, which they would want to do while you are at the clinic; or a thyroid nuclear scan, which would be done at a local clinic or hospital on another day. In the event that you do receive medical care for a thyroid or parathyroid abnormality as a result of participating in this study, we will request that you provide access to the medical records so that we may learn about your treatment. If such circumstances arise, it will be important for

us to stay in contact with you for a few months after your evaluation with us so that we receive all the records available as a result of the care you receive.

We will inform you of the results from examinations and tests in writing. In addition, the results will be sent to your personal doctor unless you do not want this done. If you do not have your own doctor, we will provide you with a list of physician referral resources in your area.

While you are at the clinic you will be asked to give a small blood sample to check your thyroid and parathyroid function. Three tubes of blood (a total of 30ml or about 2 tablespoons) will be withdrawn through a single needle stick from a vein in your arm by a doctor, a nurse, or a person certified to draw blood. This could cause some minor discomfort and/or leave a temporary bruise. There is no charge for the blood test. If you are experiencing a medical emergency because of the blood draw, dial 911 or your local operator for emergency assistance.

You may be contacted again during the next six weeks and asked to give a second blood sample. This would depend on what the first blood test showed about your thyroid or parathyroid function. This second blood test could be done in your community at your convenience. In the rare case of physical injury from the blood drawing procedure, financial compensation is not available. There is no charge for the additional blood test. If you are found to have an elevated calcium level on the second test, you will be asked to see your physician for additional diagnostic testing and treatment at your own expense. The study nurse or physicians will assist you in this process.

Only investigators from the Centers for Disease Control and Fred Hutchinson Cancer Research Center, members of the staff directly involved with this study, and staff of the quality control firm chosen to audit the data collection, will have access to the information we gather. The information you give will be combined with that given by other participants. It will be used in a statistical format when published in reports or medical journals. Therefore, none of the information supplied by a single individual will be recognizable. All information will be kept strictly confidential as required by public law PHS Act Section 308(d)(42 USC 242m(d)).

Your participation in this study is completely voluntary. Some questions in the interview are of a personal nature; you may refuse to answer any particular question or end the interview at any time. You are free to decide not to participate, and may withdraw from the study at any time without penalty.

The authorities for collecting the information in this study are Sections 301 and 306 of the Public Health Service Act. Furnishing the information, including your Social Security number (SSN), is voluntary. The SSN will be an additional item of identifying information that will assist in locating your medical records.

You will also be asked to provide information regarding your religious preference. Rates of disease have been shown in epidemiological studies to differ in members of certain religious groups which observe dietary and lifestyle restrictions. Therefore, the information on religion may be helpful in determining such differences. As with any of the questions asked, you may refuse to answer any or all of the questions, and there will be no adverse effect on you.

Through your participation in this study, you will receive a complete diagnostic work-up for thyroid disease, including an examination and laboratory testing. This includes: physical exam of thyroid gland, and blood tests for free thyroxine index (which includes total levothyroxine (T4) and resin T3 uptake), thyroid stimulating hormone (TSH), antibody to thyroid peroxidase enzyme, and serum calcium. In addition, if further diagnostic testing is recommended to determine a thyroid diagnosis, this will also be done at no cost to you. This could include any of the following: Technetium-99m scan *or* Iodine-123 scan and fine needle aspiration of the thyroid.

You will be reimbursed for travel expenses associated with your participation in this study. The knowledge gained through your participation in this study will further our understanding of the relationship between radiation and thyroid disease.

If you have questions about your rights as a research participant, please contact Karen Hansen in the Institutional Review Office of the Fred Hutchinson Cancer Research Center at (206) 667-4867. Collect calls are accepted.

If you have any questions while at the clinic, or need assistance with a medical referral, please speak with the Field Operations Coordinator. After you leave the clinic, please call 1-800-638-4837 if you have further questions.

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SIGNATURE OF HTDS STAFF MEMBER DATE

Participant's Statement

The study has been explained to me. I have had the opportunity to ask questions. I understand that future questions I may have about the research will be answered by one of the investigators listed above. Any questions I have about my rights as a research participant will be answered by Ms. Karen Hansen. Any questions I have while at the clinic will be answered by the Field Operations Coordinator. After leaving the clinic, I may call 1-800-638-4837 with further questions. I am aware that in the event of physical injury as a result of my participation in this study, financial compensation is not available. I may refuse to answer any questions or decide not to complete the interview if I wish. I may decide not to have the thyroid exam or have my blood drawn if I wish. I voluntarily consent to participate in this study and have received a copy of this consent form.

_____ _____

SIGNATURE OF PARTICIPANT DATE

Request that Results NOT be Provided to Personal Physician

I understand that it is the policy of the Hanford Thyroid Disease Study to provide my personal doctor with copies of all examination and test results from my participation in this study and to contact my personal doctor by telephone if any results are not normal. I understand that the intention of this policy is to ensure that my doctor has all information necessary to provide for my continuing medical care.

My signature below indicates that **I have refused my permission for copies of any examination or test results to be provided to my personal doctor.**

_____ _____

SIGNATURE OF PARTICIPANT DATE

_____ _____

SIGNATURE OF CLINIC OPERATIONS COORDINATOR DATE

1 copy to participant
1 copy to study files