Attachment 3A

CONSENT FORM B
Genetic Studies Among Radiologic Technologists

PURPOSE: The purpose of this research is to study the genetic or hereditary factors that may lead to increased risk of cancer. Researchers will collect material that will allow them to detect alterations in genes that may predispose to cancer or make someone more or less resistant to certain exposures. Examples are genes that may be involved in DNA repair or repair of radiation damage, such as ATM and rad51. Because every cell in your body contains genetic material, the easiest way to look for abnormalities is to look at cells in your blood. If you agree to provide a blood sample, some of your blood will be used to obtain material for genetic testing, some will be stored for later use, and some will be treated in such a way as to provide a renewable source of genetic material (a cell culture). If you had surgery to diagnose cancer, study investigators may ask your doctor or the hospital where you were treated to provide a small sample of the cancerous tissue that was removed. Your biologic specimens will be stored in a repository and will be used for medical research purposes only.

PROCEDURES: If you agree to participate, 10 ml (2 teaspoonfuls) of your blood will be drawn. The procedure will be the same as for any ordinary blood drawing. A trained health professional will clean the skin over one of the blood vessels in your arm. Then, the health professional will insert a needle into the blood vessel and draw the blood into special tubes or a syringe. Your blood will be drawn and sent to the research laboratory at no cost to you. You will also be asked to update information you provided on a previous questionnaire about your personal and family history of cancer and possible risk factors by completing the enclosed questionnaire and returning it to the University of Minnesota in the pre-addressed, postage-paid envelope enclosed.

Your blood sample will be used for medical research purposes only and you will not be given any laboratory test results. This is because for most of the tests (for example, those involving DNA repair) there is no known clinical meaning or interpretation. Some tests that we may do are also available commercially and these may have clinical relevance in terms of breast cancer risk and screening, such as tests for BRCA1 or BRCA2 mutations. However, we do not plan to provide these results because the way the samples are collected and processed in this research study are different from the way a clinical sample is handled, and the testing may not be as complete or accurate. Furthermore, we are not able to provide the appropriate genetic counseling and other support that would be needed for proper decisions about undergoing testing and interpreting the results. By agreeing to participate in this study, however, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Bruce H. Alexander at the University of Minnesota. You may call him at (800) 447-6466.

RISKS: There are no risks in this study other than those associated with a regular blood drawing. Rarely, the vein in which the needle was inserted may become sore and red. In addition, a temporary "black-and-blue" mark may develop and, very rarely, fainting may occur.

BENEFITS: There is no direct benefit to you for providing blood or tissue samples other than the satisfaction of participating in this research for the possible benefit of society. Your participation will not affect your medical care or your health benefits from the United States Government. It will not affect your association with the American Registry of Radiologic Technologists or the University of Minnesota.

COMPENSATION: In the event that you are injured during blood drawing, you or your third party payer (health insurance or Medicare) will be responsible for payment of any required medical treatment. No payment of medical treatment is available from the research sponsors.

CONFIDENTIALITY: Data from this study will be kept confidential to the extent permitted by law. This research project is covered by a Certificate of Confidentiality issued by the National Cancer Institute on behalf of the Secretary of the Department of Health and Human Services. The Certificate protects against the involuntary

release of information about you collected during the course of this study, although such information can be released if you or your guardian requests it in writing. The researchers involved in this project cannot be forced to disclose your identity or any information about you collected in this study in any legal proceedings at the Federal, State, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the Certificate does not prevent the review of your research records under some circumstances (for example, under the Federal Food, Drug, and Cosmetic Act or during the course of any internal program audit or evaluation). Research presentations and publications will present data in statistical summaries only and you will not be identified or identifiable.

CONSENT/RIGHT TO WITHDRAW: Your participation in this medical research study is voluntary and you may refuse to participate and/or withdraw your consent and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may initially decide to have your biologic samples used for research purposes but later change your mind. If you decide to withdraw, by written notification to Dr. Bruce H. Alexander, University of Minnesota, whatever remains of your biologic samples will be destroyed. Data included in previously published analyses will be retained.

CONTACTS AND QUESTIONS: This study is being conducted by the University of Minnesota in collaboration with the American Registry of Radiologic Technologists and the National Institutes of Health. If you or your doctor have any questions about this study or about your rights as a study participant, please contact Dr. Bruce H. Alexander at the University of Minnesota. You may call him at (800) 447-6466. If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview - Riverside Campus, #815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

If you are willing to participate in this study, please sign below and return this form to the University of Minnesota in the pre-addressed, postage-paid envelope enclosed. An extra copy of this consent form is enclosed for you to keep.

CERTIFICATION:

My biologic samples will be used for research purposes only and I will not be notified of any test results. My blood will be used for genetic testing that may include (for example) detecting abnormalities in DNA repair genes and other genes involved in radiation damage repair. A portion of my blood may be used to establish a renewable source of genetic material (a cell culture).

PLEASE CHECK ONE OPTION ONLY:

- ☐ I give permission to have my samples stored for genetic studies of cancer and conditions that may be related to cancer. The samples may also be used to study other health-related conditions.
  I understand that my confidentiality and identity will not be compromised.
- ☐ I give permission to have my samples stored for genetic studies of only cancer and conditions that may be related to cancer. I understand that my confidentiality and identity will not be compromised.

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Signature of Study Participant Date

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Signature of Study Investigator Date