Attachment 5B
U.S. Nuclear Medicine Technologists Study
University of Minnesota IRB Approval

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: http://research.umn.edu/subjects/

February 22, 2016

Bruce H Alexander
Environmental Health Sciences
Mayo 8807A, MMC 807
420 Delaware St SE
Minneapolis, MN 55455

RE: "Title of currently funded contract: Cancer and Other Disease Risks in Nuclear Medicine Technologists: A Feasibility Study"
"Title of overall protocol: Historical assessment of work history practices among certified nuclear medicine technologists in the U.S."
"Working title for participants: U.S. Nuclear Medicine Technologists Study"
IRB Code Number: **1510M79143**

Dear Dr. Alexander,

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project (protocol dated September 25, 2015) is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study also includes:

- Consent information sheet dated January 27, 2016
- Sample initial recruitment letter received on February 10, 2016
- "Recruitment letter/email for pretest/evaluation of on-line survey" received on December 22, 2015
- "NUCLEAR MEDICINE Sample Script Recruitment: Online Survey Evaluation" received on December 22, 2015
- "U.S. Radiologic Technologists Study" radioisotope procedures questionnaire received on October 9, 2015
- Sample follow-up letter to non-responders received on October 9, 2015

The IRB approved a waiver of documentation of consent in accord with 45 CFR 46.117 (c) (2) as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 1500 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

On January 6, 2016 the IRB approved the referenced study through January 4, 2017 inclusive.

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The Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur. Notify the IRB when you intend to close this study by submitting the Study Inactivation Request Form.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,

Melissa Nowicki, CCRP
Research Compliance Supervisor
MN/do

CC: Allison Iwan, Diane Kampa