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Supporting Statement B

CANCER RISK IN U.S. RADIOLOGIC TECHNOLOGISTS: FOURTH SURVEY (NCI)

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This submission was formerly titled:

Generic Clearance to Collect Medical Outcome and Risk Factor Data from a
Cohort of U.S. Radiologic Technologists
(2003 OMB submission)
&
Genetic Studies in a Cohort of U.S. Radiologic Technologists
(2008 OMB submission)

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Submitted by

Martha S. Linet, Principle Investigator and Chief
Radiation Epidemiology Branch
Division of Cancer Epidemiology and Genetics
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20892
E-mail: doodym@mail.nih.gov

Contact Person:
Michele M. Doody, M.S.
Contracting Officer Technical Rep
11300 Mountain View Road
Damascus, Maryland 20872
Phone: 301-414-0308
Fax: 301-414-0308

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ATTACHMENTS

Attachment 1: Information Collection Instrument
A. Core module
B. Nuclear medicine (NM) module
C. Fluoroscopically-guided (FG) interventional module

Attachment 2: Questionnaire Contact Letters

Attachment 3: Medical Validation Contact Letters

Attachment 4: HIPAA Authorization for Medical Records

Attachment 5: Institution Review Board approvals from the National Cancer Institute and The University of Minnesota

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Attachment 7: Privacy Act Memo

Attachment 8: Privacy Impact Assessment (draft) (PIA)

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The universe from which respondents are to be drawn is the previously-defined cohort of 110,418 technologists who were certified by the American Registry of Radiologic Technologists (ARRT) for at least 2 years between 1926 and 1980 and who completed at least one of three previous NCI surveys conducted during the mid-1980s (first survey), mid-1990s (second survey), and during 2003-2005 (third survey). The group being targeted for the fourth survey includes approximately 90,000 participants who are currently alive with known addresses. A response rate of at least 70% to the fourth survey is anticipated because all subjects have previously demonstrated their interest in the study by completing a previous survey. Overall response rates to the first, second, and third surveys were 68%, 72%, and 72%, respectively.

2. Procedures for the Collection of Information

Optical scan data collection instruments will be used for all information gathering. Prior to the mailing of the fourth survey, the master file of approximately 110,000 technologists who previously responded to a questionnaire will be checked against the most recent vital status records available for the study. These will include annual recertification records from the ARRT and vital status updates compiled using National Death Index, Social Security Administration, and other mortality databases. All technologists not confirmed as deceased will be eligible to receive a survey. The address file will be updated using the most recent birth month renewal update information from the ARRT and address locating searches conducted by the University of Minnesota.

An advance letter will be mailed to participants informing them about the study, the coming questionnaire, and the planned use of the information. Information from the ARRT renewals will

be used to create two versions of the advance letter, one directed at technologists who are currently registered with the ARRT, and a second version to those who have not renewed their certification in the past 12-18 months. In general, the goal of the advance letter is to let the participants know that the questionnaire is coming and encourage them to participate. By tailoring the letter based on active or inactive (not recently renewed) certification status, the message can focus on potential barriers that are different between these two groups and hopefully increase response.

Approximately 3-4 weeks after the questionnaire is mailed a follow-up letter will be sent to non-responders. After another 3-4 weeks, a second copy of the questionnaire will be mailed to persistent non-responders, and after 3-4 additional weeks a second follow-up letter will be sent to anyone who has not yet responded. To obtain essential information from chronic non-responders, an abbreviated questionnaire will be sent with a cover letter a week after a tailored (by certification status) advance letter is sent, with a follow-up letter sent 3-4 weeks later, and a second copy of the abbreviated questionnaire sent 3-4 week after that. A similar approach was utilized in the third survey to successfully achieve an overall response rate of 72%. At any point, technologists who refuse to participate will not be approached again and will be considered non-respondents in the final analysis.

Authorization to obtain medical validation information will be sought from individuals who report physician-diagnosed cancers or other medical conditions of interest. A letter detailing the request (**Attachment 3**) and a HIPAA Authorization Form (**Attachment 4**) will be mailed to appropriate technologists with a postage-paid return envelope. The signed HIPAA authorization will allow investigators access to the participant's medical records to validate the reported condition. Participants who do not return the form after the first mailing will be sent a second request letter and/or receive a telephone call to encourage response. Upon receiving the medical record release form, a letter will be mailed to the diagnosing hospital or physician of record (see

Attachment 3) with a copy of the release form and business reply envelope. Follow-up mailings and telephone calls will be made if necessary to encourage compliance. The medical records release forms and all procedures involved in obtaining, handling, storing, and using medical records have been approved by the NCI and University of Minnesota Institution Review Boards and will comply with all IRB requirements and HIPAA regulations. For subjects who live in states with accredited cancer registries, cancer validation may be sought directly from the registries since they will have already confirmed the cancers as primary malignant tumors and performed nosology coding according to the International Classification of Diseases for Oncology. This method was used successfully in the third survey.

3. Methods to Maximize Response Rates and Deal With Non-response

Prior to questionnaire mailings, additional methods for updating address information for cohort members who no longer maintain their certification with the ARRT will be used. A primary method of updating addresses will utilize the National Change of Address (NCOA) system through the U.S. Postal Service (USPS). The NCOA process improves mailing results by standardizing mailing addresses to conform to USPS requirements, including 9-digit zip codes and matching against changes of address that have been reported the USPS during the previous 48 months to obtain the current mailing addresses. Additional internet and telephone tracing resources will be used as needed to locate new addresses or phone numbers, including a major collections/tracing vendor that provides interactive access for individual searches and batched submissions to efficiently obtain updates for addresses, telephone numbers, and vital status (i.e. Social Security Death Index) for larger tracing efforts. All data acquired in these tracing activities will be maintained by the University of Minnesota in a secure manner to ensure participant privacy. Neither the NCI or other

contractors will have access to identifiable personal information. Technologists who cannot be located will be classified as non-respondents.

To improve communications and provide greater reciprocity with cohort members, study newsletters or updates are sent annually or biannually to all study participants detailing the research objectives and progress to date. Included in the newsletter updates is the address of our study-specific internet homepage (http://radtechstudy.nci.nih.gov/) on which published papers pertaining to the cohort are posted. For the planned fourth survey, we intend to create and disseminate a Winter 2011 study update before questionnaire administration.

4. Test of Procedures or Methods to be Undertaken

The fourth survey will be sent by mail to approximately 90,000 radiologic technologists who completed at least one previous survey, are known to be living, and have a current address on file. This survey underwent extensive evaluation and testing. Initial work included conducting a focus group with 11 nuclear medicine radiologists and one interventional radiologist to develop appropriate work history questions for estimating radioisotope and fluoroscopically-guided occupational radiation exposures. The information gathered, along with input from other sources, was used to refine the work history questions. These questions were also reviewed by nuclear medicine technologists at the NIH clinical center, the National Naval Medical Center, and Vanderbilt University who work with our colleagues, and their recommended revisions for improving clarity were incorporated.

Preliminary questions will be pre-tested on 9 cohort members. Study interviewers will follow-up by telephone to determine if participants had problems understanding or completing specific questions and gather any recommendations for improvement. Based on the feedback from the pre-test interviews and post-interview edits, questions will be revised to improve clarity. After

OMB approval is received, a sample of 200-300 cohort members will be asked to complete the questionnaire and will be interviewed to identify additional problems or further recommendations, and questions will be edited for clarity, as necessary. At each stage, completed pre-test forms will also be scanned for data capture. Quality assurance reviews will be conducted to verify the accuracy of the scanning and to finalize the edit/coding procedures. A 100% validation of the scanned data against the original forms will be completed and final revisions will be made to the fourth survey mail questionnaire. The scanning programs will be updated for the revised form and another 100% validation of the scanning process will be performed for a sample of forms. A Decision Log table will be created to document all edit/coding decisions. Follow-up contacts will be made by interviewers to obtain missing information and/or clarify ambiguous responses.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The University of Minnesota is under contract to the NCI (HHSN261201000139C) to support this research effort. The Project Director is Bruce H. Alexander, PhD, Division of Environmental and Occupational Health (telephone 612-625-7934, email balex@umn.edu). Information Management Services, Inc. (IMS) is under contract to the NCI (HHSN261201100007I) to provide biomedical computing support for this research effort. The IMS Project Director is Janice Beach (telephone 301-680-9770, email beachj@imsweb.com). The Contracting Officer's Technical Representative from the Radiation Epidemiology Branch, DCEG, NCI who is responsible for overseeing the data collection is Michele M. Doody, MS, Staff Scientist (telephone 301-414-0308, email doodym@mail.nih.gov). The USRT Study Principle Investigator is Dr. Martha Linet, Chief, REB; Co-lead study investigators include Drs. Alice Sigurdson, Michal Freedman, Preetha Rajaraman, and Ms. Michele Doody. Statisticians within the Epidemiology and Biostatistics Program, NCI who have provided statistical consultation and collaboration on this study are Drs. Mitchell Gail, Barry Graubard, and Mark Little. They will be consulted throughout the study as necessary.