Attachment 4A – National Cancer Institute IRB Approval (OH97-C-N053)

9/1460

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. OH97-C-N053	PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone): Michele M. Doody, NCI/REB, EPS 7040, 301-594-7203

PROTOCOL TITLE: Cancer Risk in X-ray Technologists: Second Survey

ACTION REQUESTED:
- ☐ Renew -New subject accrual to continue
- ■ Renew -Enrolled subject follow-up only
- ☐ Terminate -Protocol discontinued (describe briefly in the attached narrative.)

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
- ☐ No
- ■ Yes (Describe briefly in the attached narrative)

SUMMARY OF PROTOCOL SUBJECTS:

NIH	All Other Sites	
	150,000	Accrual ceiling set by IRB
	0	New subjects accrued since last review
	110,418	Total subjects accrued since protocol began (If accrual has been less than expected, discuss in the attached narrative.)

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
- ☐ None
- ☐ Male
- ☐ Female
- ☐ Children
- ☐ American Indian/ Alaskan Native
- ■ Other: Children
- ☐ Asian
- ☐ Black or African American
- ☐ White
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or Pacific Islander

HAVE THERE BEEN ANY CHANGES IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
- ■ No
- ☐ Yes (Explain changes in the attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
- ☐ No
- ■ Yes (Explain changes in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE THE LAST REVIEW?
- ■ No
- ☐ Yes (Identify and explain in the attached narrative)

HAVE ANY SUBJECTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?
- ■ No
- ☐ Yes (Discuss in the attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH, THAT MIGHT AFFECT THE IRB'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
- ■ No
- ☐ Yes (Discuss in the attached narrative)

CHANGE IN PRINCIPAL INVESTIGATOR: ■ No ☐ Yes
Delete: _____
Add: _____

HAVE ANY ASSOCIATE INVESTIGATORS BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
- ☐ No
- ■ Yes (Identify all changes in the attached narrative.)

CHANGE IN LEAD ASSOCIATE INVESTIGATOR: ■ No ☐ Yes
Delete: _____
Add: _____

CHANGE IN MEDICAL ADVISORY INVESTIGATOR: ■ No ☐ Yes
Delete: _____
Add: _____

CHANGE IN RESEARCH CONTACT: ■ No ☐ Yes
Delete: _____
Add: _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.):
- ■ None
- ☐ Medically indicated
- ☐ Research indicated (Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).
  - ☐ Research usage HAS NOT changed since originally approved by the IRB and RSC
  - ☐ Research usage HAS changed since originally approved by the IRB and RSC (explain changes in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE: ■ None ☐ IND ☐ IDE
FDA No. _____
Name: _____
Sponsor: _____

LIST ALL COMMERCIAL OR OTHER ENTITIES PROVIDING INVESTIGATIONAL DRUG/DEVICE:
_____

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?
- ☐ No
- ■ Yes (Identify the persons or sites and describe the collaboration in the attached narrative)

DOES THE PROTOCOL INVOLVE A DRUG/DEVICE/PRODUCT THAT MAY LEAD TO YOU OR THE NIH RECEIVING PAYMENT AND/OR ROYALTIES?
- ■ No
- ☐ Yes (Append a statement of disclosure)

HAVE ANY INVESTIGATORS DEVELOPED EQUITY, CONSULTATIVE, OR OTHER FINANCIAL RELATIONSHIP WITH A NON-NIH SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?
- ■ No
- ☐ Yes (Append a statement of disclosure)

The Principal Investigator must attach to this application: (1) a copy of the current consent/assent documents and (2) a memorandum to the IRB Chair that addresses any "yes" responses to the above questions, and that includes a concise statement regarding protocol progress to date and reason(s) for continuing the study.

SIGNATURE	Michele M. Doody Principal Investigator	Michele M. Doody Print/Type Name	Date 7/5/2006	Send to Accountable Investigator
RECOMMENDATION	Kyrtha Mabuchi Accountable Investigator	Martha S. Linet Print/Type Name	Date 7/5/2006	Send to Branch Chief, or CC Dept. Head of PI
	Kyrtha Mabuchi Branch Chief or CC Dept. Head of P.I.	Martha S. Linet Print/Type Name	Date 7/5/2006	Send to Clinical Director
APPROVALS	Frank Balis Clinical Director	F. Balis Print/Type Name	Date 8/3/06	Send to Chair, Institutional Review Board
	Chair For Institutional Review Board	Gordon Willis Print/Type Name	Date 7/25/06 Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date 8/7/06		

Clinical Research Protocol Continuing Review Application
NIH-1195-1 (3-05)

Attachment 4B – University of Minnesota IRB – Main Study (8005M02489)

Subject:
IRB Approval of Continuing Review
From:
irb@umn.edu
Date:
Fri, 15 Sep 2006 23:10:08 -0500 (CDT)
To:
dkampa@umn.edu

The IRB: Human Subjects Committee renewed its approval of the referenced study listed below:

Study Number: 8005M02489

Principal Investigator: Bruce Alexander

Expiration Date: 09/13/2007

Approval Date: 09/14/2006

Title(s):
Cancer Risk in X-Ray Technologists

U.S. Radiologic Technologists Cohort: New Strategies for Follow-up

The U.S. Radiologic Technologists Study

You may go to the View Completed section of http://eresearch.umn.edu/ to view or print your continuing review submission.

For grant certification purposes you will need this date and the Assurance of Compliance number, which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Childrens Specialty Healthcare FWA00004003). Approval will expire one year from that date. You will receive a report form two months before the expiration date.

In the event that you submitted a consent document with the continuing review form, it has also been reviewed and approved. If you provided a summary of subjects' experience to include non-UPIRTSO events, these are hereby acknowledged.

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 and adverse events should be reported to the IRB as they occur. Research projects are subject to continuing review.

If you have any questions, please call the IRB office at (612) 626-5654.

The IRB wishes you continuing success with your research.

Attachment 4C – University of Minnesota IRB – Genetic Studies (9312M07534)

Subject:
IRB Approval of Continuing Review
From:
irb@umn.edu
Date:
Thu, 5 Oct 2006 23:10:11 -0500 (CDT)
To:
dkampa@umn.edu

The IRB: Human Subjects Committee renewed its approval of the referenced study listed below:

Study Number: 9312M07534

Principal Investigator: Bruce Alexander

Expiration Date: 10/03/2007

Approval Date: 10/04/2006

Title(s):
Cancer Risks in X-Ray Technologists: Early-Onset Breast Cancer among Radiation Technologists

Genetics Studies among Radiologic Technologists

This e-mail confirmation is your official University of Minnesota RSPP notification of continuing review approval. You will not receive a hard copy or letter.
This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

You may go to the View Completed section of http://eresearch.umn.edu/ to view or print your continuing review submission.

For grant certification purposes you will need this date and the Assurance of Compliance number, which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Childrens Specialty Healthcare FWA00004003). Approval will expire one year from that date. You will receive a report form two months before the expiration date.

In the event that you submitted a consent document with the continuing review form, it has also been reviewed and approved. If you provided a summary of subjects' experience to include non-UPIRTSO events, these are hereby acknowledged.

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 and adverse events should be reported to the IRB as they occur. Research projects are subject to continuing review.

If you have any questions, please call the IRB office at (612) 626-5654.

The IRB wishes you continuing success with your research.