



Harvard Medical School

Frank P. Castronovo, Jr., Ph.D.
Radiation Safety Officer

Frank P. Castronovo, Jr., Ph.D.
Director, Health Physics Department
Radiation Safety Officer

Radiopharmacist, Radiopharmaceutical

75 Franklin Street
Boston, Massachusetts 02115
(617) 732-4057

September 5, 1991

Mr. John Kinnerman
U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Section
475 Allendale Road
King of Prussia, PA 19406

RE: Amendment for Broad License #20-17131-01

Dear Mr. Kinnerman:

The Brigham and Women's Hospital would like to amend its Broad License temporarily to include the use of Cd-109 in Atlantic City, N.J. at the Atlantic City Convention Center from October 5 through October 15, 1991. The attached material details the logistics associated with this amendment request as follows:

1. Letter to Chairman of Radiation Safety Committee from Dr. Hu discussing the investigative proposal.
2. The Radiation Safety Committee's approval letter.

The responsible individuals concerning radiation safety will be Dr. Hu (the Permit holder) and Dr. Burger, who will be acting on behalf of the Brigham and Women's Hospital in matters of radiation safety. Personnel associated with the instrument will be issued radiation badges and records will be maintained.

The \$370 amendment fee is also attached.

Sincerely,

Frank P. Castronovo, Jr., Ph.D.
Radiation Safety Officer

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PDR FOIA
STOLL 92-58 PDR

FPC/rac

Attachments (3)

cc: B. Leonard Holman, M.D.
Florence Stepian
Howard Hu, M.D.
NRC File

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BRIGHAM
AND
WOMEN'S
HOSPITAL



Leonard Holman, M.D.
Chairman, Radiation Safety Committee
Brigham and Women's Hospital
75 Francis St.
Boston, MA 02115

Sept. 4, 1991

Dear Dr. Holman,

We thank you for the opportunity to present our proposal in the manner you requested.

In summary, we currently are using a K-X-ray fluorescence (K-XRF) instrument to measure bone lead levels in vivo as part of ground-breaking epidemiologic research on the toxicologic consequences of lead accumulation. This K-XRF instrument uses a sealed ¹⁰⁹Cd source that is currently at 160 mCi strength to generate the energy for this work. Its current usage has the approval of the BWH Committee for the Protection of Human Subjects and the Radiation Safety Committee in three human protocols (protocols 91-2316-4, 90-2966-1, and 90-4032-2), under my radiation permit (#801, see Appendix A).

In mid-August, we were offered a unique opportunity to measure bone lead levels among occupationally-exposed workers during the annual convention of the International Brotherhood of Carpenters and Joiners, scheduled to take place on Oct. 6-11, 1991 in Atlantic City. Bone lead measurements would be taken as part of a comprehensive health screening research program funded by the National Institute for Occupational Safety and Health. The information derived from the bone lead measurements would be invaluable from a research stand-point.

We have applied to the BWH Committee for the Protection of Human Subjects for a modification of protocol 90-4032-2 in order to do this research (Appendix B). The Committee is waiting for approval from the Radiation Safety Committee before proceeding (see letter, Appendix C). We anticipate no problems, as the research is essentially identical to the original research of protocol 90-4032-2, except that it would be performed off-site.

In order to use our K-XRF instrument for this project, we also need the Brigham and Women's Hospital to apply to the Nuclear Regulatory Commission for a permit to temporarily extend their site license to cover this work. We contacted John

Kimmerman of the NRC Materials Safety Section and he verbally indicated his willingness to receive such an application. He further noted the similarity of such an application to one just approved by the NRC in which a K-40F instrument with a ^{109}Cd source is being used for a survey in Pennsylvania under an extended site license of the University of California at San Francisco (see copy of amended license, Appendix D)

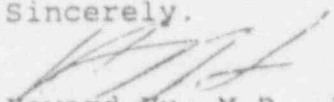
Since time was growing short for an application, we then moved rapidly to contact Dr. Castronovo regarding the possibility of extending the site license of the Hospital. After considering our request and consulting with you, he impressed upon us the immense importance to the Hospital of ensuring the security of the ^{109}Cd source.

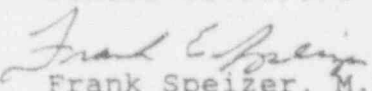
Therefore, in conjunction with our proposed hosts, we have organized a detailed plan for handling and securing this source that is summarized in Appendix E entitled "Chain of Custody and Security for ^{109}Cd Source". Should this project come to pass, we give our solemn assurances to adhere to this plan with absolute strictness.

Time is obviously growing very short. We hope that you will find our arrangements satisfactory, and will consider polling the other Radiation Safety Committee members as soon as possible if warranted. Please contact Dr. Hu if you have any questions or concerns whatsoever. He will be available 24-hrs by BWH beeper #190.

Thank you.

Sincerely,


Howard Hu, M.D., M.P.H., Sc.D.
Associate Physician
Assistant Professor of
Occupational Medicine, Harvard
School of Public Health


Frank Speizer, M.D.
Co-director, Channing
Laboratory
Associate Physician
Professor of Medicine

cc: Dr. Eugene Fraunwald
Dr. Frank Castronovo

BRIGHAM AND WOMEN'S HOSPITAL

Permit to use Radioactive Material
(Human Use)

A permit is hereby issued authorizing the individual(s) named herein to receive, acquire, own, possess, transfer and import the radionuclides listed below and to use such material for the purpose(s) and at the place(s) designated below. This permit is subject to all applicable rules and regulations of the Hospital and in particular to the provisions of Title 10, Code of Federal Regulations (CFR), "Standards for Protection Against Radiation," Title 10 CFR, Part 20 "Medical Use of Byproduct Material" and of the Rules and Regulations to Control the Radiation Hazards of Radioactive Materials and of Machines which Emit Ionizing Radiation adopted by the Department of Public Health, Commonwealth of Massachusetts. Radioactive material specified herein shall be used only on the Hospital premises and by, or under the supervision of, the named individuals.

Radiopharmaceuticals for use in humans shall be acquired from a supplier who certified the pharmaceutical quality and assay of such material. If radiopharmaceuticals are prepared for human use, the methods of establishing pharmaceutical quality shall be approved by the Pharmacy Committee.

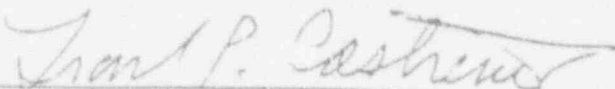
INDIVIDUAL USER(S)

1. Howard Hu, M.D.
Name
2. Medicine
Department or Laboratory
3. 601*
Permit Number
4. September 1991
Expiration Date
5. X-Ray Fluorescence Studies in Human Bones
Authorized Use

Approved by:



B. Leonard Holman, M.D.
Chairman, Radiation Safety Committee



Frank P. Castronovo, Jr., Ph.D.
Radiation Safety Officer

*replaces previously numbered SHD-04-A

Date Issued: May 11, 1989 - revised January 12, 1990

Appendix B



Department of Medicine

Division of Occupational Medicine

Dr. Howard H. H. H.

Boston, Massachusetts 02115

Oct 11, 1991

Keith Marcotte
Chairperson, Committee for the
Protection of Human Subjects from Research Risks
Brigham and Women's Hospital

Aug. 15, 1991

Re: Protocol 90-4032-2

Dear Mr. Marcotte,

We would like to apply for an addition/modification to this protocol.

In summary, as you know, the protocol as it exists concerns the recruitment of workers occupationally-exposed to lead to come to our facility at the Brigham and Women's Hospital.

We would like permission to apply the same protocol to workers who will be evaluated in a special project. Atlantic City, October 6-11, 1991. In this project, funded by the National Institute for Occupational Safety and Health, members of the International Brotherhood of Carpenters and Joiners will be coming for an in-depth health screening. As part of the screening, we will measure their bone lead levels with our K-X-ray fluorescence (K-XRF) instrument. Our segment of the screening will take place in a specially-arranged secure room in the hotel where the main screening will take place. All safeguards will be in place as required by the Nuclear Regulatory Commission. The same procedure will be used as we currently use at the Brigham and Women's Hospital, except that we will decrease measurement time to 20 minutes (to save time during the screening).

Attached is an informed consent that is tailored to this project.

Since the screening will take place October 6, we would like to secure approval for this project as soon as possible. Please let me know if you need any further information. Thanks again.

Sincerely,

Howard H. H. H.

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RESEARCH CONSENT FORM

DATE PREPARED: 8/15/91APPROVED FOR USE BY THE BRIGHAM AND WOMEN'S
HOSPITAL HUMAN RESEARCH COMMITTEE ON:PROJECT TITLE: Measuring Lead Burden with
X-ray FluorescencePRINCIPAL INVESTIGATOR:
Edward Hu, MDCO-INVESTIGATOR(S): Marinelle Payton MD,
Hirokatsu Watanabe MD, Karl Kelsey MD,
Scott Slater BA, Marisa Barr MS, Sudha Kotna BA
Barbara Gales MD

STUDY REPRESENTATIVE(S): _____

CARPENTERS BQ E LEAD STUDYPurpose

We would like permission to enroll you as a participant in this research study. The purpose is to assess the usefulness of a new instrument, called X-Ray Fluorescence, for measuring the amount of lead stored in your skeleton.

When you are exposed to lead, it is stored in the body (mostly in the skeleton), from where it can slowly be released and cause damage. Unfortunately, blood lead tests have only a limited ability to tell us how much lead is stored in the body. X-Ray Fluorescence, however, can directly measure how much lead is stored in your skeleton.

Procedure

If you agree to participate, you will visit our X-Ray Fluorescence facility during your health screen. There, you will sit in a special chair with velcro straps to hold one your legs still. The X-Ray Fluorescence instrument will be positioned on your shin, and a 20 minute measurement will be recorded. A 20 minute measurement will also be taken from your knee. The evaluation is then over. The measurement can be interrupted at any time so that you can get up, go to the bathroom, stretch, etc.

If you have any questions or would like additional information regarding this study, you can contact Dr. Hu during the convention through the registration desk of the Atlantic City Convention Center. After the convention, you can page him through our hospital operator (617-732-6987 during weekdays, 8:30am - 5:30pm).

Risks and Discomforts

The only risk from this procedure is from the extremely low-dose radiation that is used in the procedure. The risk from the entire measurement is equivalent to one tenth the radiation risk of a dental x-ray (or one fiftieth the risk of a chest x-ray).

Benefits

The major potential benefit for you would be additional knowledge regarding the amount of lead accumulation in your body that may also influence your medical management. In addition, the knowledge gained is extremely

important for the future health of society.

Standard Paragraphs

The following paragraphs contain standard information which, in the opinion of the Human Research Committee of the Brigham and Women's Hospital, generally applies to persons involved in a research study and are required on all consent forms.

In the event that at any time during the course of this project, you feel you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject, or feel under duress to continue against your wishes, the Executive Secretary of the Human Research Committee or representative is available to speak with you during normal working hours (8 a.m. to 4:30 p.m.) at 617-732-5740.

Confidential information contained in your medical record may not be furnished to anyone unaffiliated with the Brigham and Women's Hospital without your written consent, except as required by law or regulation.

A signed copy of this consent form will be made available to you.

You are free to withdraw your consent and to discontinue participation in this project at any time, and such discontinuance will not affect your regular treatments or medical care in any way.

Investigator's Statement

I have fully explained the procedures, identifying those which are investigational, and have explained their purpose. I have asked whether or not any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date

Signature of responsible investigator

Subject's Statement

I have been fully informed as to the procedures to be followed, including those which are investigational, and have been given a description of the attendant discomforts, risks and benefit to be expected and the appropriate alternate procedures. In signing this consent form, I agree to participation in this study and I understand that I am free to withdraw my consent and have this study discontinued at any time. I understand also that if I have any questions at any time, they will be answered.

Date

Signature of patient (or subject)

Appendix C



BRIGHAM
AND
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Committee for the Protection
of Human Subjects
from Research Risks

10 Vining Street
Boston, Massachusetts 02113
(617) 333-3740

Ruth E. Tuomala, M.D., Chairperson
Keith A. Marcotte, Executive Secretary
Mary B. d'Entremont, Coordinator

TO: Howard Hu, M.D.

FROM: Joan Maider
Protocol Administrator

DATE: August 27, 1991 *mm*

RE: "Measuring Lead Burden with X-Ray Fluorescence
(91-4032-4)

The amendment you requested to the above referenced study was reviewed by the Human Research Office. We are awaiting approval of the Radiation Safety Committee. When that is received, we can then process your amendment. There can be no patient enrollment until we hear from the Radiation Safety Office.

Thank you for your cooperation with this matter.



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