THE GEORGE WASHINGTON UNIVERSITY HOSPITAL

UHS Universal Health

IR 2007001

June 12, 2007

RECEIVED REGION 1
2007 JUN 15 AM 10: 42

Penny Lanzisera
Senior Health Physicist
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19405-1415

SUBJECT: NRC Inspection May 29/30, 2007
Requested Additional Information

REFERENCE: DISTRICT Hospital Partners, L.P.
D/B/A The George Washington University
NRC License No. 08-30607-01
Docket No.: 030-35424

Dear Ms. Lanzisera:

In the exit interview on May 30, 2007, you requested additional information on the following items, which are listed below: All of your concerns have now been corrected.

I. A nuclear medicine technologist was observed not wearing finger dosimetry while in the hot lab. Our new dosimetry provider, Landauer, Inc., has been supplying us with one-size fits all type ring badges. The ring dosimeters assigned to our nuclear medicine technologists are small and uncomfortable to wear. As a result some of the technologists are in the habit of taking off the ring badges when they are not in the hot lab/imaging rooms and are not handling radiopharmaceuticals. But no one complained about this problem to the Radiation Safety Office. As soon as during your inspection we were aware of this problem, we ordered large sized ring badges for those individuals. They are now wearing new large sized ring badges.

II. On June 1, 2007, the RSO provided radiation safety training to the nuclear medicine technologists. Our scintimammography technologist from the Breast Imaging Center, who is a certified RT in mammography, also attended the training session. In addition, the RSO also conducted a separate hands-on training for her on how to use a survey meter, use of scale setting, and use of check source and how to perform a laboratory survey.

III. All check sources for calibration that are used in the Nuclear Medicine area are stored in a leaded drawer in the hot lab. We posted a label on the lead drawer with the name of each the isotope, ID number, activity and calibration date.

IV. The Gadolinium-153 (GD-153) check source that was stored in the hot lab has been transferred to the Sealed Sources Storage room # 22010.

V. The minutes of the Radiation Safety Committee that deal with security of quantities of concern amount of radioactive material were marked as "Security Related Information- Withhold From Public Disclosure Under 10 CFR 2.390". Personnel who have access to the information were informed about NRC's concern.

NMSS/RGNI MATERIALS-004

VI. The survey meter (Ludlum-3, probe model 44-9, serial # 169472) in room DC227A in the Breast Imaging Center was due for calibration on May 3, 2007. The meter has been removed and sent for calibration. In the mean time a meter that was calibrated in a known radiation field using Cs-137 beam calibrators is being used to survey radiation level in room DC227A.

Please note that the Radiation Safety Office personnel conduct weekly contamination survey of the Breast Imaging room DC227A, and swipes are counted using a Gamma Counter.

I have asked the Vendors to calibrate the survey meters that are used to perform required radioactive package survey, radiation level survey and patient release survey etc. to a known radiation field using Cs-137 beam calibrators. The survey instruments calibration shall comply with 10 CFR, part 35.61 and 10 CFR part 20 requirements.

VII. At present pre-calibrated unit doses of Tc-99m sestamibi (miraluma) (30 milliCurie dose per patient) in syringes are received in the Nuclear Medicine hot lab for scintimammography patients. All the doses are hand carried to the Breast Imaging room in the Ambulatory Care Center.

At the time the unit doses are picked up by the scintimammography technologist, each labeled syringe is matched with the ticket corresponding to the prescription number on the syringe label. The syringe is measured in the Nuclear Medicine dose calibrator and the current time and the measured activity are recorded on the matching ticket. Each individual patient dose is decay corrected at the time of injection and must be within + 10% of the prescribed dose, otherwise the dose has to be adjusted.

VIII. During recent NRC inspection of the Breast Imaging room the technologist was busy with a scintimammography patient and got confused about your query of the IRB protocol and use of the consent form. As per Rachel Brem, M.D., authorized user physician, the IRB protocol has been completed as of January 2007 (Attachment). Please note that on December 20, 2004, The Radiation Safety Committee of the GWU hospital approved safe use of ionizing radiation aspect of Dr. Brem's IRB protocol.

IX. As per discussion with you on May 30, 2007, Mr. Howard Griffith, Senior Physicist, Division of Radiation Oncology has already faxed you additional information that you wanted on the seedSelectron device, its acceptance test, QA check, etc.

If you have any questions or need additional information, please call me at 202-715-4959.

Sincerely,

A. Chowdhury

Anisuzzaman Chowdhury, Ph.D.
Radiation Safety Officer

cc: Trent Crable
Esma Akin, M.D.

The George Washington University
WASHINGTON DC
MEDICAL CENTER

MEDICAL FACULTY ASSOCIATES ADMINISTRATION

June 7th, 2007

To whom it may concern:

Please be advised that we are no longer accepting clinical patients for Breast Specific Gamma Imaging protocol. Attached you will find a notice to the Institutional Review Board showing we are closed to enrollment.

Sincerely,

Rachel F. Brem, MD

2150 PENNSYLVANIA AVENUE, N.W., SUITE 10-403 • WASHINGTON, DC 20037 • (202)994-4022/23 • FAX (202)994-8435

The George Washington University
Institutional Review Board

Progress Report

Please choose one: ☒ Continuing Review ☐ Study Closure ☐ Study Termination
(Modifications requests must be submitted separately, using the Modification Request form.)

OHR IRB Number: 060005 Expiration Date: 01/31/07 IRB Risk Assessment: High risk
Protocol Title: The Use of Scintimammography as an Adjunctive Screening Procedure in Women Who are at High-Risk for Breast Cancer

Principal Investigator: Rachel F. Brem, MD
Department/School: Department of Radiology, Breast Imaging & Intervention
Sponsor: Bristol Meyers Squibb Medical Imaging, Inc.

General Information Relating to the Study (Check one):

☐ Active (still enrolling subjects)

☐ All research related activities ***completed***. Closure of file requested.

☐ Closed to enrollment, **open** subjects are still on the protocol regimen/intervention.

☐ Terminated, explain: **{type here}**

☒ Closed to enrollment, **open** for follow-up of subjects.

☐ Closed to enrollment, **open** for analysis of identifiable/coded data only.

Current version/date of the IRB approved protocol and consents: 05/30/06

Subject Demographics **Subject accrual ceiling approved by the GWU IRB: 500**

		Since Last Review	Combined Total
1.	Number of subjects accrued at GWU:	64	497
2.	Number of subjects accrued elsewhere (if known/applicable):	n/a	n/a
3.	Number of subjects withdrawn/dropped at GWU:	0	1
4.	Number of subjects withdrawn/dropped elsewhere(if applicable)	n/a	n/a
5.	Number of serious adverse events (SAEs) at GWU:	0	1
6.	Number of SAEs elsewhere (if known/applicable):	n/a	n/a
7.	Number of deaths at GWU:	0	0
8.	Number of deaths elsewhere (if known/applicable):	n/a	n/a

Please submit to OHR, in Room 613, Ross Hall.

OHR OFFICE USE ONLY

Determination:

☒ Full IRB (1/9/07)
☐ Reviewed and re-approved via expedited process.
☒ Study re-approved for 12 months. ***This IRB re-approval expires on:*** 1/31/08
☐ File Closed

IRB Approval of request:

Parenti
Chair/IRB Designee

Signature

1/31/07
Date

This document serves as verification of Continuing Review Approval, Closure.

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Regulatory Criteria for IRB Continuing Review of Research

1. Provide a summary of any expected/unexpected serious adverse events and their likely cause; unanticipated problems involving risks to subjects or others; withdrawal of subject(s) from the research, including reasons; and/or complaints about this research study since last IRB review. **None since the last review.**

   Were all events, problems, withdrawals, or complaints reported promptly to the IRB per GWU's Problem Reporting Policy? ☐ Yes ☒ No, if not, please explain **None**

2. Summarize (including multi-center/DSMB reports (if applicable), monitoring reports, preliminary results, abstracts of recent scientific literature with full citation), and any other information that has become available since the last IRB review, that may affect the risks and benefits associated with the research or subjects' willingness to continue in the study. **(Attach list of any unexpected AEs not previously reported.) See attached research summaries.**

3. Describe modifications to the research since last IRB review (e.g., change in research team members, subject recruiting; advertising; inclusion/exclusion criteria; protocol; informed consent; documentation of informed consent; privacy/confidentiality protections, safety monitoring): **The research coordinator was changed to Beverly Burroughs. She has left MFA and recruitment is currently underway. In the interim, the previous research coordinator has assumed her duties. We will inform the IRB when the position is filled.**
   As of 1/2/2007 The Research Coordinator is now Kristen Dixon and a modification form is in submission.

   Were all above-described modifications reviewed and approved by the IRB prior to implementation?
   ☒Yes ☐ No (If no, please explain in the space provided below:)

Signature: _____ **Date** 1/22/07
Principal Investigator Signature

(Note: Student researchers must obtain signature of Faculty Advisor/Designee listed as the principal investigator (PI) for this study.)

Please complete document and send it to:
The Office of Human Research
Ross Hall, Suite 613
2300 Eye Street, NW
Washington, DC 20037

Phone: 202.994.2715
Fax: 202.994.0247
Email: ohrirb@gwumc.edu