North Shore LIJ
North Shore-Long Island Jewish Health System

Institutional Review Board
Committee C
FWA #00002505
Office of the Institutional Review Board
5 Dakota Drive, Suite 307
Lake Success, New York 11042
Phone: 516-719-3100
Fax: 516-719-3110

10/15/2007

Joseph Diamond, M.D.
Cardiology Rm 228 K. Hinds
Long Island Jewish Medical Center
270-05 76th Avenue
New Hyde Park, NY 11040

RE: **IRB #:** 04.08.141T
Protocol Title: The Prognostic Value of Pharmacologic Nuclear Stress Testing in Elderly Patients Undergoing Moderate to High-Risk Surgery
Expiration Date: 10/9/2008

Dear Dr. Diamond:

This is to advise you that the Progress Report submission received 10/1/2007 for the above referenced study was reviewed by the Institutional Review Board on 10/10/2007 and the following determination was made:

Pre Meeting Action: Expedited Approval for the following:

1. This study is closed to enrollment, open for follow-up and data analysis only.

Please note:

All conditions of approval previously established by the IRB for this research project continue to apply. The Institutional Review Board - Committee C will be notified of this action at its meeting on 10/30/2007.

NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
3. Reporting serious adverse events.
4. Renewing the study at the interval set by the Institutional Review Board (currently 12 months). The expiration date for this study is listed above. You should submit a progress report to the Institutional Review Board at least two months prior to expiration of the study. Failure to receive notification that it is time to renew does not relieve you of your responsibility to provide the IRB with the Progress Report in time for the request to be processed and approved prior to your expiration date.
5. **Prior to implementation, any changes made to studies utilizing the GCRC and/or TAP must have GAC and/or COPP, as well as IRB approval.**

Sincerely,

Elaine V. Neal, CIP
Assistant Director, Office of the Institutional Review Board

Internal #: 6321

The Office of the IRB no longer sends a hard copy of documents which have been electronically transmitted.
These are the only copies of the regulatory documents you will receive.

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10/15/2008

Joseph Diamond, M.D.
Cardiology Rm 228 K. Hinds
Long Island Jewish Medical Center
270-05 76th Avenue
New Hyde Park, NY 11040

RE: **IRB #:** 04.08.141T
Protocol Title: The Prognostic Value of Pharmacologic Nuclear Stress Testing in Elderly Patients Undergoing Moderate to High-Risk Surgery
Expiration Date: 10/14/2009

Dear Dr. Diamond:

This is to advise you that the Progress Report submission received 10/6/2008 for the above referenced study was reviewed by the Institutional Review Board on 10/15/2008 and the following determination was made:

Pre Meeting Action: Expedited Approval for the following:

1. Study closed to enrollment, open for follow-up and data analysis only.

Please note:.

All conditions of approval previously established by the IRB for this research project continue to apply. The Institutional Review Board - Committee will be notified of this action at its meeting on 10/21/2008.

NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
3. Reporting serious adverse events.
4. Renewing the study at the interval set by the Institutional Review Board (currently 12 months). The expiration date for this study is listed above. You should submit a progress report to the Institutional Review Board at least two months prior to expiration of the study. Failure to receive notification that it is time to renew does not relieve you of your responsibility to provide the IRB with the Progress Report in time for the request to be processed and approved prior to your expiration date.
5. **Prior to implementation, any changes made to studies utilizing the GCRC and/or TAP must have GAC and/or COPP, as well as IRB approval.**

IMPORTANT REMINDER: The International Committee of Medical Journal Editors (ICMJE) requires registration of clinical research studies meeting specific guidelines prior to publication. Please see ICMJE requirements for registration of clinical trials at http://www.icmje.org. To register your trial: http://prsinfo.clinicaltrials.gov . **You must register your trial PRIOR TO ENROLLING SUBJECTS.**

Sincerely,

Elaine V. Neal, CIP, EMT-B
Assistant Director, Office of the Institutional Review Board

Internal #: 8540

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