



North Shore-Long Island Jewish Health System

**Institutional Review Board**

**FWA #00002505**

Office of the Institutional Review Board  
350 Community Drive, 4<sup>th</sup> Floor  
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To: Amgad N. Makaryus, MD  
Cardiology  
North Shore University Hospital  
300 Community Drive  
Manhasset, NY 11030

From: Martin L Lesser, PhD  
Chair, Institutional Review Board

Date: Thursday, April 22, 2010

RE: **IRB #:** 10-073B  
**Protocol Title:** Geometric Comparison of the Mitral Tricuspid Valve Annulus: Insights from 3  
Dimensional Transesophageal Echocardiography  
**Expiration Date:** 4/21/2011

Dear Dr. Makaryus:

The above referenced project meets the criteria outlined in 45 CFR 46.110 and 21 CFR 56.110 for EXPEDITED REVIEW and has been approved. The following category(ies) apply(ies) to the project:

45 CFR 46.110 (5): **(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).**

Pre Meeting Action: Expedited Approval. Approval of this project includes:

1. Protocol version 4/1/10
2. This study has been granted a Waiver of Consent and HIPAA Authorization.

Please note:

*The Institutional Review Board - Committee will be notified of this action at its meeting on 5/20/2010.*

Subject recruitment methods are appropriate, there is equitable selection of subjects, and there are provisions to protect and maintain the confidentiality of data and research participants.

*Investigators are reminded that research must be conducted in accordance with all applicable Department of Health and Human Services regulations 45 CFR 46, Food and Drug Administration regulations 21CFR 50, 21CFR 56, 21 CFR 812, and the Health Insurance Portability and Accountability Act (HIPAA).*

***All studies are subject to audits by the Office of Research Compliance and/or Institutional Review Board to confirm adherence to institutional, state, and federal regulations governing research. All research studies are expected to conform to Good Clinical Practice (GCP) guidelines.***

**NOTE:** This approval is subject to recall if at any time the conditions and requirements as specified in the IRB Policies and Procedures are not followed (see next page and web site: <http://www.northshorelij.com/body.cfm?ID=2804>)

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.

Revised: December 2009

Internal #: 12467

**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>. Our organization account is in the name of the North Shore-Long Island Jewish Health System. To register your trial: <http://prsinfo.clinicaltrials.gov>. **You must register your trial PRIOR TO ENROLLING SUBJECTS.**

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