Baystate Medical Center

Institutional Review Board

DATE:	December 23, 2010
TO:	amir lotfi, md
FROM:	Baystate Health IRB #1
STUDY TITLE:	[169361-6] Effect of Remote Ischemic Preconditioning on the Incident of Atrial Fibrillation in Patients Undergoing Coronary Artery Bypass Graft Surgery, A Randomized Controlled Trial
IRB REFERENCE #:	BH-10-212
SUBMISSION TYPE:	Response/Follow-Up
ACTION:	APPROVED
APPROVAL DATE:	December 22, 2010
EXPIRATION DATE:	October 25, 2011
REVIEW TYPE:	Expedited Review
PROJECT RISK LEVEL:	More than Minimal Risk

Thank you for your submission of Response/Follow-Up materials for this research study. The Baystate Health IRB #1 has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

The following items were included in this submission:

- Other - response to irb (UPDATED: 11/8/2010)
- Protocol - grafts protocol revised (UPDATED: 11/8/2010)

Proposed changes to the research must be submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to subjects.

Any Unanticipated Problems Involving Risks to Subjects or Others, Deviations from the approved research, Non-Compliance, and Complaints must be reported to the IRB in accordance with Baystate HRPP policies and procedures. If this study includes ongoing oversight by a Data Safety Monitoring Board (DSMB) or other such committee, reports generated by the DSMB or oversight committee must be submitted to the IRB.

Continuations must be submitted 60 days prior to the expiration date noted above. The federal regulations provide for no grace period. Failure to obtain approval for continuation of your study prior to the expiration date will require discontinuation of all research activities for this study, including enrollment of new subjects.

If you would like to have this study registered in CIS for obtain Research Alerts, please provide the IRB office with the following information: **IRB#, Title, Short Title, PI, PI phone number; e-mail addresses of those individuals who should receive the Alert and any special information that you would like care providers to be aware of.** You can e-mail the above information to Marybeth.Kennedy@baystatehealth.org who will notify you when the Alert has been created. It will be your responsibility to associate subjects with the alert.

The consent document(s) will be forwarded to **Interpreter and Translation Services Department** for translation. Please allow for a six week turn around time. Once the translated documents have been provided, the IRB will forward the documents to you. It will be your responsibility to submit the translated documents to the IRB via an Amendment in order to formalize approval. If this service is not needed for this study contact Lisandra.Gonzalez@baystatehealth.org within 5 days of receipt of this letter.

If you have any questions regarding this approval, please contact the IRB office at (413) 794-4356.