North Shore-Long Island Jewish Health System

Institutional Review Board
FWA #00002505
Office of the Human Research Protection Program
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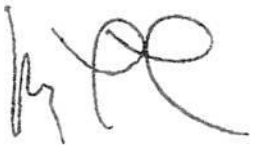
To: Keith Sultan, MD
Gastroenterology
North Shore University Hospital
300 Community Drive
Manhasset, NY 11030

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



Date: Friday, April 04, 2014

RE:
IRB #: 12-070B
Protocol Title: Comparison of the Diagnostic Yield and Clinical Outcomes between Standard 8 Hour Capsule Endoscopy and the New 12 Hour Capsule Endoscopy
Expiration Date: 4/3/2015

Dear Dr. Sultan:

This is to advise you that the Progress Report submission received 2/14/2014 for the above referenced study was reviewed by the Institutional Review Board on 4/4/2014 and the following determination was made:

Pre Meeting Action: Expedited Approval for the following:

1. Protocol (version 4/12/13).
2. Study closed to accrual on 6/30/13.
3. The following investigators are approved to participate on the study: Keith Sultan, Bethany DeVito, Stuart Akerman, Merajur Rahman.

This study qualifies for expedited review per: 45 CFR 46.110(8): Continuing review of research previously approved by the IRB: where the research is permanently closed to the enrollment of new subjects.

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 4/17/2014.*

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 unanticipated problems involving risk to subject or others.
4. Renewing the study at the interval set by the Institutional Review Board. 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 TAP must have 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.**

Internal #: 25635