



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: Hallie Kassan, MS, CIP
Director, Office of the Human Research Protection Program

Date: Tuesday, January 06, 2015

RE: **IRB #:** 14-700
Protocol Title: Combination Therapy for Inflammatory Bowel Disease in the Community Setting
Expiration Date: 1/7/2016

Dear Dr. Sultan:

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.

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

1. Application Protocol (version 12/14/14)
2. This study has been granted a waiver of informed consent and HIPAA authorization.
3. The following investigators are authorized to participate: Keith Sultan, Joshua Berkowitz, Sundas Khan.

The following category applies to the project: 45 CFR 46.110 (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).

The Institutional Review Board - Committee will be notified of this action at its meeting on 1/8/2015. This study has not been approved for the inclusion of pregnant women, children, or prisoners. If you would like to include these populations, please notify the IRB for further instruction.

The IRB approval expiration date is listed above. As a courtesy, approximately 60 to 90 days prior to expiration of this approval, the Office of the IRB will send an e-mail reminding you to apply for continuing review. Failure to receive renewal notification does not relieve you of your responsibility to provide the Progress Report to the IRB in time for the request to be processed and approved prior to your expiration date. **It is your responsibility to apply for continuing review and receive continuing approval for the duration of the study.** Lapses in approval should be avoided to protect the safety and welfare of enrolled subjects.

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 21 CFR 50, 21 CFR 56, 21 CFR 312, 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.

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>)

Internal #: 28795

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 subjects or others.
4. 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>. 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.**