Institutional Review Board
FWA #00002505
Office of the Institutional Review Board
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Manhasset, New York 11030
Phone: 516-719-3100 or 516-562-3100
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North Shore-Long Island Jewish Health System

To: Mala Sachdeva
Nephrology
100 Community Drive
Great Neck, NY 11021

From: Victor Fornari, MD
Chair, Institutional Review Board

Date: Tuesday, August 06, 2013

RE: **IRB #: 13-402A**
Protocol Title: Obesity Trends-Analysis of UNOS DATABASE

Dear Dr. Sachdeva:

The above referenced project meets the criteria outlined in 45 CFR 46.101 for **EXEMPTION**. The following category applies to the project:

45 CFR 46.101 (b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

You have been issued a waiver of authorization as per 45 CFR 164.512 for the use and disclosure of information for research purposes.

This constitutes institutional approval of the data collection as being exempt from the requirement of IRB review, approval, and oversight. It is your responsibility to notify the IRB in writing of <u>any</u> changes or modifications made in the research study design, procedures, etc. which do not fall within one of the exempt categories. Such changes necessitate a new, complete IRB submission. If the IRB receives no correspondence on this study for three years, the file will be closed.

The Institutional Review Board - Committee will be notified of this action at its meeting on 8/7/2013.

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 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. 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)

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 the 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.**