NEW YORK METHODIST HOSPITAL

INSTITUTIONAL REVIEW COMMITTEE 506 SIXTH ST BOX 159008 BROOKLYN NY 11215-9008 TEL 718/780-5575

MEMORANDUM

DATE:	May 15, 2014
TO:	Manuel Gonzalez, MD Department of Gastroenterology
FROM:	Eric Balmir, MS, PharmD, CIM IRB Chairperson
RE:	IRB APPROVAL LETTER
STUDY TITLE:	[518027-1] Colorectal Cancer Screening Rates in an Urban Ambulatory Clinic by Internal Medicine Residents Compared to the National Average; Identifying Barriers to increased Colorectal Cancer Screening
IRB REFERENCE #:	518027
SUBMISSION TYPE:	New Project
FWA NUMBER:	00002741
ACTION:	APPROVED
APPROVAL DATE:	May 14, 2014
EXPIRATION DATE:	January 27, 2015
REVIEW TYPE:	Expedited

Thank you for your submission of New Project materials for this research study. New York Methodist Hospital IRB has APPROVED your submission at the January 27, 2014 IRB meeting pending certification by all members of the study team. The IRB has verified that all members have been certified as of May 14, 2014. 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.

This study has received Expedited Approval based on the applicable federal regulation. The following materials for the study were approved:

- Protocol: [518027-1] Colorectal Cancer Screening Rates in an Urban Ambulatory Clinic by Internal Medicine Residents Compared to the National Average; Identifying Barriers to increased Colorectal Cancer Screening
- Data Collection as per screen shot (with password protected software on a password protected computer in a secure area.

The requirement for written consent has been waived in accordance with federal regulations 45CFR46.116(d). You have also been authorized to use protected health information in this study inaccordance with HIPAA Privacy Rule 164.512 (i).

Please note that this office prior to initiation must approve any revision to previously approved materials. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Serious adverse events should be reported to the IRB within 24 hours of your becoming aware of the event. Any unanticipated problem not deemed serious in nature should be reported to the IRB within 20 working days. You should use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. You will receive an email from the IRB requesting that you access IRBNet to complete a progress report for this procedure. In order to avoid any interruption in your continuance with the study, please be sure to submit the report *before* the study expiration date.

If you have any questions, please contact Pearlia Fullard at (718) 780-5559 or pcfullar@nyp.org. Please include your study title and reference number in all correspondence with this office.

cc: *Dr. Gaeta, Chairperson Research Committee*
C. Caraway, Director Grants Management & Compliance

Member

New York-Presbyterian Healthcare System
Affiliate: Weill Medical College of Cornell University