WAYNE STATE UNIVERSITY

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NOTICE OF FULL BOARD APPROVAL

To: Adhip Majumdar
Internal Medicine
VA Medican Center; Rm-B4238

From: Lawrence R. Crane, M.D. or designee_____
Chairman, Medical Institutional Review Board (M1)

Date: March 20, 2013

RE:	IRB #:	030113M1F(V)
	Protocol Title:	Racial Disparity in Colorectal Cancer: Molecular Mechanisms
	Funding Source:	Sponsor: NATIONAL CANCER INSTITUTE Sponsor: NATIONAL INSTITUTES OF HEALTH
	Protocol #:	1302011753
Expiration Date:		March 06, 2014
Risk Level / Category:		Research involving greater than minimal risk presenting no prospect of direct benefit, but likely to yield generalizable knowledge about the participant's condition

The above-referenced protocol and items listed below (if applicable) were **APPROVED** following *Full Board Review* by the Wayne State University Institutional Review Board (M1) for the period of 03/20/2013 through 03/06/2014. This approval does not replace any departmental or other approvals that may be required.

- The IRB has determined that all appropriate elements were included in the informed consent form, and are included in the informed consent process.
- Protocol (received in the IRB Office 2/7/13), and revised Protocol Summary Form (received in the IRB Office 3/20/13)
- HIPAA Summary Form (received in the IRB Office 2/7/13) and Authorization for Release of Identifiable Health Information for Research Purposes
- VA Research Consent Form (dated December 2012)
- A waiver of consent for screening purposes has been granted according to 45CFR 46 116(d) and justification provided by the Principal Investigator in the Protocol Summary Form. This waiver satisfies: 1) risk is no more than minimal, 2) the waiver does not adversely affect the rights and welfare of research participants, 3) the research could not be practicably carried out without the waiver, and 4) Providing participants additional pertinent information after participation is not appropriate.
- A waiver of HIPAA Authorization for screening purposes has been granted in accordance with the Privacy Rule and justification provided by the Principal Investigator in the HIPAA Summary Form. This waiver satisfies: 1) the use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, 2) the research could not be practicably conducted without the waiver, 3) the research could not be practicably conducted without access and use of the PHI, 4) adequate steps taken to protect identifiers from improper use or disclosure and 5) adequate plan for destroying identifiers or links.
- Participant Materials: Volunteering in Research VA Brochure
- Data Collection Tools: Data Collection Sheet

° Federal regulations require that all research be reviewed at least annually. You *may* receive a *"Continuation Renewal Reminder"* approximately two months prior to the expiration date; however, it is the Principal Investigator's responsibility to obtain review and continued approval ***before*** the expiration date. Data collected during a period of lapsed approval is unapproved research and can *never* be reported or published as research data.

° All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.

- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (http://www.irb.wayne.edu/policies-human-research.php).

NOTE:

1. Upon notification of an impending regulatory site visit, hold notification, and/or external audit the IRB Administration Office must be contacted immediately.
2. Forms should be downloaded from the IRB website at **each** use.