WAYNE STATE UNIVERSITY

HUMAN INVESTIGATION COMMITTEE
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Full AAHRPP Accreditation

# NOTICE OF EXPEDITED APPROVAL

**To:** Fadi Antaki
Internal Medicine
VA Medical Center C-3825

**From:** Lawrence R. Crane, M.D. or designee Dawn Bielawski (cas) for
Chairperson, Medical Institutional Review Board (M1)

**Date:** March 01, 2011

**RE:** HIC #: 025911M1E(V)
Protocol Title: Instrumental & Human Factors Affecting Yield of Colonoscopy
Funding Source:
Protocol #: 1102009404

**Expiration Date:** February 29, 2012

**Risk Level / Category:** Research not involving greater than minimal risk

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The above-referenced protocol and items listed below (if applicable) were **APPROVED** following *Expedited Review* (Category (5)*) by the Chairperson/designee *for* the Wayne State University Institutional Review Board (M1) for the period of 03/01/2011 through 02/29/2012. This approval does not replace any departmental or other approvals that may be required.

- This protocol has met all criteria at 45 CFR 46.110 and 111 for expedited review approvals.
- A waiver of consent 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 and 3) the research could not be practicably carried out without the waiver.
- Receipt of a HIPAA Summary Form
- A waiver of HIPAA Authorization 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.
- Receipt of a research protocol (dated December 10, 2010)

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- 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 HIC **BEFORE** implementation.
- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the HIC Policy (http://www.hic.wayne.edu/hicpol.html).

**NOTE:**

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

*Based on the Expedited Review List, revised November 1998