Institutional Review Board
M.C. 26-03
100 North Academy Avenue
Danville, PA 17822
570 271 8663Tel
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Geisinger Health System

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Approval Notice
Initial Review (Response From PI) - Expedited Review

September 30, 2010

Michael J. Komar, MD
Gastroenterology & Nutrition
Geisinger Clinic
100 North Academy Avenue, M.C. 21-11
Danville, PA 17822-2111
Phone: (570) 271-6856

RE: Research Protocol **# 2010-0299**
"Retrospective analysis to assess the incidence and risk factors associated with colonic perforation after screening ,diagnostic or therapeutic colonoscopy"

Dear Michael J. Komar, MD:

Members of Institutional Review Board (IRB) #2 reviewed and approved your research protocol under expedited review procedures [45 CFR 46.110(b)(1) and/or 21 CFR 56.110(b)(1)] on September 28, 2010. You may now begin your research.

Your research was found to have met the following specific category:

> 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).

NOTE: If you need to recruit more subjects than was noted in your IRB approval letter, you must submit an amendment requesting an increase in the number of subjects PRIOR to enrollment of additional subjects.

Please note the following information about your approved research protocol:

Protocol Approval period:	September 28, 2010 - September 27, 2011
Consent:	Waived under Regulation 45CFR46.116(d)(1-4)
HIPAA Research Authorization:	Waived under Regulation 45CFR164.512(i)(2)(ii) and (iii)
Recruiting Material(s):	Records (e.g. Medical, Employment, School)

Research Protocol:	Dated: 09/21/2010
Sponsor:	Departmental
Approved Subject Enrollment #:	**200**
Performance Sites:	Geisinger Medical Center
Retrospective Date Range:	**1/1/2002 – 8/24/2010**

Please remember to:

→ Use your **research protocol number (2010-0299)**on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements of the, " **Investigator Responsibilities, Protection of Human Research Subjects**"

Please note that the Geisinger IRB has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

If you have any questions or need further help, please contact the Office of Research Programs staff at 570-271-8663. Please send any correspondence about this protocol to the Office of Research Programs at 26-03.

Sincerely,

Lauren A. Johnson-Robbins, MD
Chair, IRB # 2
Institutional Review Board

Enclosure(s): (1) **Investigator Responsibilities, Protection of Human Research Subjects**
(2) IRB Approved stamped data dictionary (9/23/10 version) and Charlson Comorbidity Score

cc: Dennis Torretti, M.D. (01-41)
Uzair Hamdani, MBBS MD

Investigator Responsibilities
Protection of Human Research Subjects

(Version1.1 – February 20, 2004)

The Institutional Review Board (IRB) recently reviewed and approved your research. The IRB reviews research to ensure that the federal regulations for protecting human research subjects outlined in Geisinger's policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56) as well as other requirements are met. Geisinger's Federalwide Assurance (FWA) (FWA# 00000063) awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written pledge to follow federal guidelines for protecting human research subjects in accordance with the principles of the Belmont Report. **All investigators must read both the Belmont Report and the FWA to understand their responsibilities in conducting human subject research**. Both documents are available on the Clinical Research website at and in hard copy. Some of the responsibilities investigators have when conducting research involving human subjects are listed below:

1. Conducting the Research. You are responsible for making sure that the research is conducted according to the IRB approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.

2. Subject Enrollment. You may not recruit or enroll subjects prior to the IRB approval date or after the expiration date of IRB approval. All recruitment materials for any form of media must be approved by the IRB prior to their use. If you need to recruit more subjects than was noted in your IRB approval letter, you must submit an amendment requesting an increase in the number of subjects.

3. Informed Consent. You are responsible for obtaining and documenting effective informed consent using **only** the IRB-approved consent documents, and for ensuring that no human subjects are involved in research prior to obtaining their consent. Please give all subjects copies of the signed consent documents. Keep the originals in your secured research files for at least six (6) years. When appropriate, you should place a copy of the consent document in the subject's medical record.

4. Continuing Review. The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period.** Prior to the date on which the IRB approval of the research expires, the Office of Research Programs will send you a reminder to submit a Continuing Review Application.

5. Although the Office of Research Programs sends reminders, **it is ultimately your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in IRB approval does not occur.** If IRB approval of your research lapses, you must stop new subject enrollment, and contact the Office of Research Programs immediately.

6. Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of subjects, subject population, consent document, instruments, surveys or recruiting material), you must submit the amendment to the IRB for review using the Amendment/Modification Form. You **may not initiate** any

amendments or changes to your research without first obtaining written IRB review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to subjects and the IRB should be immediately informed of this necessity.

7. Adverse or Unanticipated Events. Any serious adverse events, subject complaints, and all unanticipated problems that involve risks to subjects or others, as well as any research related injuries, occurring at Geisinger or at other performance sites must be reported to the IRB within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the IRB's requirements for protecting human research subjects. The only exception to this policy is that the death of a Geisinger research subject must be reported within 24-48 hours of discovery. All reportable events should be submitted to the IRB using the Adverse Event Problem Report Form available on the Geisinger website.

8. Research Record Keeping. You must keep the following research related records, at a minimum, in a secure location for a minimum of six years: the IRB approved research protocol and all amendments; all consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence to and from the IRB.

9. Reports to FDA and Sponsor. When you submit the required annual report to the FDA or you submit required reports to your sponsor, you **must** provide a copy of that report to the Office of Research Programs for the IRB. You may submit the report at the time of continuing IRB review.

10. Provision of Emergency Medical Care. When a physician provides emergency medical care to a subject without prior IRB review and approval, to the extent permitted by law, such activities will not be recognized as research nor the data used in support of research.

11. Final reports. When you have completed (no further subject enrollment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the IRB.

12. On-Site Evaluations, FDA Inspections, or Audits. If you are notified that your research will be reviewed or audited by the FDA, the sponsor, any other external agency or any internal group, you **must** inform the Office of Research Programs immediately of the impending audit/evaluation.

If you have any questions or need assistance, please contact the Office of Research Programs staff at (570) 271-8663.