

The University of Kansas Medical Center

Human Research Protection Program

October 3, 2011

Project Number: 12897
Project Title: Pilot Study to Evaluate Comprehensive Stool Analysis Results from a Racially and Ethnically Diverse Population
Sponsor: None
Protocol Number: N/A
Primary Investigator: Allen Greiner, M.D.
Department: Family Medicine
Meeting Date: 09/27/2011
HSC Approval Date: 09/30/2011
HSC Expiration Date: 09/29/2012
Type of Approval: Expedited f (3), (5) & (7)

Dear Investigator:

This is to certify that your research proposal involving human subject participants has been reviewed and **approved** by the KUMC Human Subjects Committee (HSC). This approval is based upon the assurance that you will protect the rights and welfare of the research participants, employ approved methods of securing informed consent from these individuals, and not involve undue risk to the human subjects in light of potential benefits that can be derived from participation.

Approval of this research is contingent upon your agreement to:

- (1) Adhere to all KUMC Policies and Procedures Relating to Human Subjects, as written in accordance with the Code of Federal Regulations (45 CFR 46).
- (2) Maintain copies of all pertinent information related to the research study including, but not limited to, video and audio tapes, instruments, copies of written informed consent agreements, and any other supportive documents in accordance with the KUMC Research Records Retention Policy.
- (3) Report unanticipated problems to the HSC by completing the Internal or External HSC Unanticipated Problem/Adverse Event reporting form, as applicable.
- (4) Submit deviations from previously approved research activities which were necessary to eliminate apparent and immediate dangers to the subjects by using the KUMC Protocol Deviation Report.
- (5) Submit Amendments to the HSC for any proposed changes from the previously approved project using the Request for Amendment form. Changes may not be initiated without prior HSC review and approval, unless a delay in implementation would place subjects at risk.
- (6) Submit Continuing Review Form (CR Form) to the KUMC HSC before the expiration date. Federal regulations and HSC policies require continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

If you have any questions regarding the human subject protection process, please do not hesitate to contact our office.

Very truly yours,



Daniel J. Voss, M.S., J.D.
IRB Administrator

CONSENT FORM

Evaluation of Comprehensive Stool Analysis Results from a Racially and Ethnically Diverse Population

HSC # 12897

INTRODUCTION

As an eligible participant (age 50-75) who has agreed to be contacted for research purposes through the Family Medicine Research Division or the Department of Preventive Medicine, you are being invited to participate in a research study about comprehensive stool analysis. This research study is directed by K. Allen Greiner, MD, MPH, as the principal investigator. We expect to enroll approximately 20 participants for this pilot study.

You do not have to participate in this research study. Before you make a decision to participate, you should read the rest of this form. The main purpose of this research is to benefit future patients and society in general. You might get personal benefit from participating in this study, but you should understand that the purpose of research is to create new knowledge.

BACKGROUND

Colorectal Cancer is the third most common cancer diagnosed in men and women and is the third leading cause of cancer-related death. African American men suffer greater rates of colorectal cancer, later stage at diagnosis, and are more likely to die from the disease than African American women or people of other racial/ethnic groups. Recent studies have shown that there are differences in gut bacteria between individuals with and without colorectal cancer. The difference in colorectal cancer rates and severity in African American men may, in part, be due to differences in gut bacteria that can be evaluated and detected by comprehensive stool analysis. For this study, we will perform baseline comprehensive stool analysis to categorize bacterial profile differences in a diverse population.

PURPOSE

The purpose of this pilot study is to examine relationships between clinical and socio-demographic characteristics and comprehensive stool analysis results in a racially and ethnically diverse population. Comprehensive stool analysis is useful for monitoring the general health of the digestive tract, and may play a role in early detection and prevention of digestive system symptoms including colorectal cancer. This study will also compare comprehensive stool analysis results and information about diet and physical activity reported through a medical, diet, and exercise survey and a three-day food diary. We believe that comprehensive stool analysis results will be associated with patient characteristics or with diet and lifestyle choices.

PROCEDURES

If you are eligible and decide to participate in this study, your participation will last no longer than 30 days. You will answer survey questions regarding personal and family medical history, diet and exercise. Surveys will be conducted over the phone or in person and will last approximately 30 minutes. You will also provide a stool sample for comprehensive stool analysis. Stool samples are collected at home using a kit. This kit contains detailed instructions for stool collection. If you have had a colonoscopy in the last five years, we will also attempt to access your medical records to confirm the results of this screening test. For us to obtain this information, we will ask you to sign a Release of Information form.

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RISKS

The risks of participating in this project are minimal. The survey could cause some anxiety or discomfort but should pose no physical risk.

NEW FINDINGS STATEMENT

You will be informed if any significant new findings develop during the course of the study that may affect your willingness to participate. As part of the comprehensive stool analysis, a fecal occult blood test (one of the recommended screening methods for colorectal cancer) will be conducted. Should those results come back positive, you will be informed and assisted in getting the results to your primary physician or clinic.

BENEFITS

You will receive information about comprehensive stool analysis should you participate in this study. It is hoped that additional information gained in this research study may increase understanding of how to best communicate with patients about the importance of understanding and monitoring digestive health. In light of these potential benefits, the minimal study-specific risks are reasonable.

ALTERNATIVES

Participation in this study is entirely voluntary. Deciding not to participate will have no effect on the care or services you receive at your primary care clinic or at the University of Kansas Medical Center.

COSTS

There is no cost to you associated with your participation in this research study.

PAYMENT TO SUBJECTS

You will receive a \$20 gift card for your time and inconvenience when you complete the phone or in-person questionnaire to begin the study. You will receive another \$30 gift card for your time and inconvenience when you complete the over-the-phone survey 7-10 days after you have responded to the initial survey. The KUMC Research Institute will be given your name, address, social security number and the title of this study to allow them to keep track of gift cards you receive for participating in the study. Study payments are considered taxable income.

INSTITUTIONAL DISCLAIMER STATEMENT

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

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CONFIDENTIALITY AND PRIVACY AUTHORIZATION

Efforts will be made to keep your personal information confidential. Researchers cannot guarantee absolute confidentiality. If the results of this study are published or presented in public, all information that identifies you will be removed.

The privacy of your health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission ("authorization") for KUMC to use and share your health information for the purposes of this research study. If you decide not to sign the form, you cannot be in the study.

To do this research, we need to collect health information that identifies you. We will collect information from activities described in the Procedures section of this form.

Your study-related health information will be used at KU Medical Center by Dr. Greiner, members of the research team, the University of Kansas Hospital Medical Record Department, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

All study information that is sent outside KU Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and disclose your health information remains in effect until the study is complete and the results are analyzed. After that time, information that personally identifies you will be removed from the study records.

QUESTIONS

You have read the information in this form. Dr. Greiner or his associates have answered your question(s) to your satisfaction. You know if you have any more questions, concerns or complaints after signing this form you may contact Dr. Greiner or one of his associates at (913) 945-6733. If you have any questions about your rights as a research subject, you may call (913) 588-1240 or write the Human Subjects Committee, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

Your participation in this study is voluntary and the choice not to participate or to quit at any time can be made without penalty or loss of benefits. Not participating or quitting will have no effect upon the medical care or treatment you receive now or in the future at your primary care clinic and the University of Kansas Medical Center. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have a right to change your mind about allowing the research team to have access to your health information. If you want to cancel permission to use your health information, you should send a written request to Dr. K. Allen Greiner, Department of Family Medicine, Mailstop 3064, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160.

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If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

CONSENT

Dr. K. Allen Greiner or his associates have given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

I freely and voluntarily consent to participate in this research study. I have read and understand the information in this form and have had an opportunity to ask questions and have them answered. **I will be given a copy of the consent form to keep for my records.**

Type/Print Subject's Name

Signature of Subject

Time

Date

Type/Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

I am willing to be re-contacted at a later date (up to 3 years from now) about other health promotion studies conducted by the University of Kansas Medical Center faculty and staff. I understand that my name, address, phone and 2 friend/relative contacts will be kept on file for this purpose.

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Yes

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No

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