

Department of Veterans Affairs		VA Research Consent Form	
Title of Study	Racial Disparity in Colorectal Cancer: Molecular Mechanisms		
Participant's Name			
Participant ID Number		Date:	
Principal Investigator	Adhip Majumdar, Ph.D., D.Sc.	VAMC: John D. Dingell VA Medical Center	

You are being asked to volunteer to take part in a research study at the John D. Dingell VA Medical Center. Participation in this research study is voluntary. This consent form gives you information about the study. It is important that you read and understand the information on this form.

About 140 people will take part in this study at the John D. Dingell VA Medical Center. This study is being sponsored by the National Cancer Institute, National Institutes of Health (NIH). The NIH is paying for the John D Dingell VA Medical Center to do this study.

Please read this form and ask any questions you may have before agreeing to be in the study.

PURPOSE OF RESEARCH STUDY:
 You are being asked to be in this research study because you are between 40 and 80 and you are scheduled to have a colonoscopy at the John D. Dingell VA Medical Center.

The study is attempting to evaluate factors that affect the risk of developing colon polyps and colon cancer in people of different races. The presence or absence of those factors does not mean that you have cancer at this time or will have cancer in the future.

In this research study, and after the clinical examination of your colon is completed, we will obtain small samples from the lining of the colon (biopsies) and analyze them for different markers that are related to colon polyps and colon cancer. We will also obtain a small sample from the fluid suctioned from your colon during colonoscopy.

STUDY PROCEDURES:
 If you agree to take part in this research study, you will be asked to give Dr. Majumdar and his research team permission to review your medical records to obtain the results of today's colonoscopy. We will also seek your permission to enter the results of your colonoscopy (e.g. number of polyps found, location of polyps found) and the pathologist's description of the biopsies into an electronic database. A subject number will be assigned to you, so your participation in the study will be anonymous.

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Also, if you agree to take part in this research study, we will remove eight (8) biopsies (very small, pinhead size tissue samples) from normal appearing areas of the lining of the colon (large intestine) at the end of the regular colonoscopy procedure. We will also obtain a small sample from the fluid suctioned from your colon during colonoscopy, which would otherwise be discarded.

The fluid and tissue samples will be analyzed for different markers that are possibly related to the development of colon polyps and colon cancer in the laboratory of Dr. Adhip Majumdar, located in the Detroit VAMC, 4th floor; Room: B-4247. You will not be informed as to the results of this analysis because the results will be supportive of a hypothesis and more extensive research will need to be done. You will be able to obtain the pathology results of any polyp removed at the time of the colonoscopy from the Gastroenterology specialist who has performed the procedure.

RISKS:
In addition to the usual risks of colonoscopy (including a small risk of bleeding and a very rare risk of perforation) which have been discussed with you by the doctor performing the procedure, your participation in this study includes a risk of breach of confidentiality of your private information. We will take all measures to minimize this risk by keeping the data secured and locked in a research office and by labeling all samples with a study code and not with your name or other identifiers. There may also be risks involved from taking part in this study that are not known to researchers at this time.

BENEFITS:
As a participant in this research study, there will be no direct benefit for you; however, information from this study may help better understand the mechanisms for the development of colon polyps in individuals of different races and hopefully help us prevent colon cancer or detect it at an early stage in the future.

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<p>STUDY COSTS: The research biopsies and other procedures that are part of this research project will be performed at no cost to you.</p> <p>ALTERNATE COURSES OF ACTION: Your participation in this study is voluntary. You may have the colonoscopy procedure that you are scheduled for without the research biopsies being taken.</p> <p>STATEMENT OF RESEARCH RESULTS: When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs obtained at the time of your colonoscopy are used for research or educational purposes, your identity will be protected.</p> <p>SPECIAL CIRCUMSTANCES: You will not receive any financial or proprietary interest in the samples or in any products or processes that may result from research on the samples.</p> <p>COMPENSATION: You will not be paid for taking part in this study.</p> <p>CONFIDENTIALITY: All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. Federal agencies including, but not limited to, the FDA, OHRP, ORO, and the VA Office of the Inspector General (OIG) may have access to the records. Information stored on a computer will be password protected. Research records will be kept in accordance with the VA record retention policy. Until that time your research records will be kept in a secure location, in a locked cabinet, in the locked research office.</p>			
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<p>RESEARCH PARTICIPANT'S RIGHTS:</p> <p>You have read each page of this consent form or each page has been read to you. A member of the research team has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been told that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.</p> <p>If you have any questions, concerns or complaints about this study now or in the future, you may contact Dr. Adhip Majumdar or one of his research team members at the following phone number (313) 576-4460. If you have questions or concerns about your rights as a research participant or the validity of this study, the Chair of the Investigational Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research team, you may call the Research Compliance Officer at (313) 576-4467 to ask questions or voice concerns or complaints or you may call the Patient Advocate at (313) 576-1000, ext. 65158.</p> <p>The results of this study may be published, but your records will not be revealed unless required by law. In case there are medical problems or questions, you have been told you can call Dr. Majumdar at (313) 576-4460 during the day and the GI physician on-call at (313) 576-1000 after hours.</p> <p>The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. No reimbursement, compensation or free medical care is offered by Wayne State University or the National Institutes of Health (NIH). You may be among the veterans required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.</p>			
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<p>Your signature on this form indicates that you have had this research explained to you and your questions about it answered, and you voluntarily consent to participate in this study. You will receive a signed copy of this consent form.</p>			
<div> <div>x</div> <div>x</div> <div>x</div> </div>			
Research Participant's Signature		Date	Time
<div> <div>x</div> <div>x</div> <div>x</div> </div>			
Signature of person obtaining consent (Study personnel must be approved by IRB.)		(Print Name)	Date
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<div> <div>VERSION NUMBER: 2</div> <div>August 2014</div> </div>			