MedStar Health
Research Institute

MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board

Date:	November 30, 2010
To:	Kristi Graves, PhD Oncology 3300 Whitehaven ST NW, Suite 4100 Washington, DC 20007
From:	Melissa Lewis Project Coordinator Institutional Review Board
Title:	Colon Cancer Survivorship Experiences
IRB#:	2010-076
Annual Approval Date:	November 17, 2010
Expiration Date:	November 16, 2011
Action:	Expedited Continuing Review Active Informed Consent HIPAA

Your above referenced protocol and consent form were approved for continuation through expedited review by Dr. Vera Malkovska, IRB Chairman or the designee on November 26, 2010 and reapproved for a maximum of one year.

This is to inform you that you may continue your project.

Approval for this study is through **November 16, 2011.** The IRB requires that you submit an application for annual renewal at the end of the approval period and/or at study completion. Please note that this office will automatically terminate the project on the date stated above, unless reviewed and re-approved by the IRB. ***It is the PI's responsibility to submit the application for annual renewal and the appropriate IRB forms at least <u>one month</u> before the expiration date.***

Please remember to:

1. Seek and obtain prior approval for any modifications to the approved protocol.
2. Promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the Institutional Review Board within 7 calendar days. This includes information obtained from sources outside MedStar Health Research Institute and Georgetown University that reveals previously unknown risks from the procedures, drugs or devices used in this study.

30035

CC: IRB file

ECR 30035

RECEIVED

OCT 29 2010

INSTITUTIONAL REVIEW BOARD

TO: Chair, MedStar Research Institute-Georgetown University Oncology IRB

FROM: Kristi D. Graves, Ph.D.

RE: Continuing Review Submission for the study "*Colon Cancer Survivorship Experiences.*" **IRB # 2010-076**

DATE: October 28, 2010

We would like to submit for review by the IRB our continuing review form (Form D-2) and supporting documents for our study entitled "Colon Cancer Survivorship Experiences," IRB # 2010-076.

As noted in the D-2 form, we have some participants who have not yet provided written informed consent. Per our approved IRB protocol, we are first obtaining verbal consent from participants who agree to enroll in the study. Prior to using the data, we obtain written informed consent. To date, 31 of 40 enrolled participants have provided both written and verbal informed consent. The remaining 9 individuals have provided verbal consent and have their written informed consent and online survey completion both pending. We have been actively following up with these individuals by telephone to determine if they have any remaining questions or concerns about continuing involvement in the study.

This study remains active for subject enrollment. We have begun to analyze the qualitative telephone interview data but expect a few additional participants to enroll and complete the online survey. As noted above, we have enrolled 40 individuals to date.

With this submission, we have included the following documents:

Annual Renewal and Form D-2:

1. IRB Application Form D-2
2. Copy of most recent IRB Application (Form D-1)
3. Current IRB-approved stamped informed consent document
4. One clean copy of the IRB-approved informed consent document for stamping
5. One clean copy of HIPAA Authorization for stamping
6. Summary of results to date (Item #8 on the D-2 Form)
7. Current Study Specific Disclosure Forms
8. Certificate of Completion for Protection of Human Research Subjects

Thank you for your consideration. Please let me know if there are any questions I can answer.

Best,

Kristi D. Graves, Ph.D.
Cancer Control Program
202-687-1591
kdg9@georgetown.edu

☐ Noted
☒ Approved
☐ Approved
☐ Approved
☐ Approved

DATE: 11/26/2010
w/modifications:
Exempt
Expedited

☐ Disapproved

Chair, Institutional Review Board

RESEARCH AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

Who may have and use my health information?

I agree to allow **Kristi D. Graves, Ph.D., Richard A. Winett, Ph.D., and Sarah A. Kelleher, B.A.** and their staff (together called "Researchers"), as well as (when applicable) the other people or companies listed below, to receive, use, have and disclose my personal health information (as permitted below) for the reason(s) described in the Informed Consent Form used for this study (identified above) and as needed to conduct the research.

- The study Sponsor (**The Fisher Center for Familial Cancer Research**), including others working with the Sponsor (together called the "Sponsor");
- Laboratories and other individuals and organizations that look at my health information in connection with this study;
- Members and staff of the Institutional Review Board(s), Ethics Committee(s), Data Safety Monitoring Boards (DSMB) and all other review boards or persons who watch over how the research is performed and/or monitor the safety and success of the research, including the Institution that approves this study;
- The Patient Advocate or Research Ombudsman (people who watch out for my best interest);
- The United States Food and Drug Administration (FDA), any other Federal or State Agencies that watch over the safety of the study and how the study is managed or run, and/or governmental agencies in other countries which fill similar oversight roles;
- Others: N/A

Who may give (release or disclose) my health information?

I wish to allow **the Familial Cancer Registry, Clinical Genetics Program staff, and Cancer and Molecular Epidemiology Shared Resource at Georgetown University Medical Center**, to give my health information in my medical or other records to the Researchers, Sponsor(s) and others listed above, for the research purposes described in the Informed Consent Form used in this study and as otherwise described below.

What health information may be used for this research study? (Check all that apply)

☐ All my personal information in my medical records or other health care related records requested by the Researchers to be able to do the research described in the Informed Consent Form for this study;

☒ All my personal information made or collected during the research described in the Informed Consent Form for this study; *and/or*

☒ Only the following information: Name, address, phone number, date and stage of colon cancer diagnosis, genetic risk information (if applicable), date of birth, gender, colon cancer treatment.

**Note: if any of the above records contain any information about HIV/AIDS status, cancer diagnosis, drug/alcohol abuse, sexually transmitted disease, or includes records or information from another healthcare provider, I agree that I am hereby authorizing the release and use of this information.*

What could happen if I agree to this use or disclosure of my health information?

- There is the possibility that Federal privacy laws (laws that protect the privacy to my personal health information) may no longer protect it from being given to another person, class of persons, and/or company.
- Once information that could be used to identify me has been removed and my information is no longer identifiable (connected to my identity), the information that remains is no longer protected by this Authorization (agreement) and may be used and given by the Researchers and Sponsor to others, including for other research reasons.
- The Researchers and Sponsor have agreed that no publication or presentation of the research will reveal my identity without my separate specific written permission and authorization (agreement) (even if I revoke (take back) this Authorization (agreement)).

What rights do I have?

- While my health care and benefits relating to healthcare outside the study will not be affected if I do not sign this form, I understand I have the right to refuse to sign this Authorization (agreement), but that I will not be able to participate in the research referred to in this form.
- I may change my mind and cancel this agreement at any time. To cancel this agreement, I must write to: **Kristi D. Graves, Ph.D., Cancer Control Program, Georgetown University, Suite 4100, 3300 Whitehaven Street NW, Washington, DC 20007.** However, if I cancel this agreement, I may no longer be allowed to participate in the research and may no longer receive research-related treatment. Also, even if I cancel this agreement, the information already obtained may remain a part of the research as necessary to preserve the integrity of the research study.
- I will be given a copy of this agreement after I have signed it.

When does this Authorization expire?

This Authorization has no expiration date, but shall expire at the end of the research study identified above.

By signing below I represent and warrant that I have authority to sign this document and authorize the use or disclosure of PHI and that there are no restrictions that would prevent me from authorizing the use or disclosure of this PHI.

Signature of Participant *(or Participant's Personal Representative)* _____ Date _____

Printed Name of Participant *(and if applicable print name of* _____ Representative's authority to sign for Participant, *(parent,*

Study Number: 2010-076

Title: *Colon Cancer Survivorship Experiences*

Informed Consent for Clinical Research
MedStar Research Institute/Georgetown University Medical Center

INSTITUTION: **Georgetown University Medical Center / Georgetown University Hospital**

INTRODUCTION

You are invited to consider participating in this study. The study is called ***"Colon Cancer Survivorship Experiences."*** Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary;

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;

(c) You may decline to participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form. The investigators (persons in charge of this research study) are Kristi D. Graves, Ph.D., Richard S. Winett, Ph.D., and Sarah Kelleher.

The research is being sponsored by the Jess & Mildred Fisher Center for Familial Cancer Research. The Jess & Mildred Fisher Center for Familial Cancer Research is called the sponsor and Virginia Tech, a collaborating research site, is being paid by the Jess & Mildred Fisher Center for Familial Cancer Research to conduct this study. Kristi D. Graves is the primary investigator of the project at Georgetown University.

WHY IS THE STUDY BEING DONE?

Hereditary Non-Polyposis Colon Cancer (HNPCC) is a hereditary cancer syndrome caused by a genetic alteration for which genetic counseling and testing is available. HNPCC is the most common hereditary cause of colon cancer, accounting for 5% of all colon cancer diagnoses. Because individuals with colon cancer who have the HNPCC syndrome (or have it in their family) are at increased risk for being diagnosed with colon cancer again in the future, it is important to learn more about the lifestyle behaviors of these survivors. Specifically,

learning more about diet and exercise practices in this group will help us to improve the psychological and health-related outcomes of colon cancer survivors. This research is being done because currently there is little to no research on the health behaviors of this unique colon cancer survivor group. **In this study we are trying to learn about how you have adjusted to your cancer diagnosis. We are also interested in looking at whether your health behaviors have changed since your cancer diagnosis and treatment, and if so, how they have changed, so that we can understand how to most effectively help people make healthy lifestyle changes in order to improve their quality of life and therefore lead healthier lives.**

You are being asked to participate in this study because you are a colon cancer survivor who has had HNPCC genetic counseling. Both people who have and who have not had genetic testing for HNPCC are eligible.

You may not participate in this study if any of the following apply to you:

You are currently undergoing treatment for your colon cancer diagnosis;
You are unable to provide informed consent.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About 80 subjects will take part in this study. Participants are men or women, aged 18 or over, able to read and understand English, not cognitively impaired, and patients who are enrolled in the Familial Cancer Registry or seen through the Clinical Genetics Program at Georgetown University's Lombardi Comprehensive Cancer Center.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, we will ask you to complete a one time online survey asking questions about your thoughts, attitudes, and opinions toward your cancer diagnosis, cancer risk due to genetics, and health and lifestyle behaviors. In this one time survey, we will ask for your attitudes about cancer risk due to genetics. We are also interested in talking to a small number of participants after they complete the survey. At the end of the one time online survey, we will ask if you might be willing to complete a brief follow-up telephone survey. This telephone survey is completely optional and you will be open to accept or decline the option for the follow-up telephone survey.

HOW LONG WILL I BE IN THE STUDY?

Participation involves a one time online survey that takes 45-60 minutes to complete. For individuals who agree to further contact for the telephone interview, those contacted will complete a telephone call that would take about 20 to 30 minutes.

You can stop participating at any time. You can also complete the one time online survey and refuse to participate in the follow-up telephone interview. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first. There are no consequences related to withdrawal from this study.

WHAT ARE THE RISKS OF THE STUDY?

Risks related to participating in the survey are minimal. You may feel slightly uncomfortable answering certain questions about cancer risk, genetic testing, or your health behaviors. You may of course choose to not answer any question you do not want to answer. We will make every effort to protect your confidentiality.

The proposed research does not include genetic testing; however, it does involve participants who may have previously had genetic counseling and testing for HNPCC. As such, risks of participating in research involving individuals who have already had genetic testing include the use of personal, genetic information for unauthorized or discriminatory purposes. All research personnel who will have access to genetic information about you are ethically and legally obligated to maintain the confidence of that information. However, there can be no absolute guarantees that the genetic information will remain confidential.

A new federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally offers the following protections:

- Health insurance companies and employer-based group health plans may not request your genetic information that we get from this research.
- Health insurance companies and employer-based group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. The protections offered by GINA apply regardless of when the research that obtained the genetic information was conducted, even if prior to the effective date.

Be aware that this new law does not protect you against discrimination on the basis of your genetic information by companies that sell life insurance, disability insurance, or long-term care insurance.

In addition, there is a risk that being in a genetics study can cause psychological distress or tension with other family members. Members of the research team are available to provide appropriate referrals to you or to members of your family if anyone would like additional information or support related to their genetic or other health status.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will be no direct medical benefit to you. We cannot promise that you will experience medical benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Whether you participate in this study or not, you will continue to receive the usual medical care provided to you by your doctor. There are no alternatives except not participating in this study.

WHAT ABOUT CONFIDENTIALITY?

Every effort will be made to protect all of the information you share with us to the extent allowed by law. However, we cannot guarantee absolute confidentiality. This study does not involve your medical records in any way. Information provided by research study participants is stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research or consent documents for quality assurance and data analysis include groups such as: The Jess & Mildred Fisher Center for Familial Cancer Research, Joint MedStar Research Institute-Georgetown University Oncology Institutional Review Board (IRB), Virginia Polytechnic Institute and State University IRB. All of the information you provided will be coded with an identification number and your name will not be on any study related materials.

DATA SECURITY

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage:

All information kept on a computer will be accessed only through secure servers available only by password. All study computers are kept in individual locked offices.

WHAT ARE THE COSTS?

There are no costs associated with participating in this study. Participants will be provided with a $10 gift card to one of several vendors.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for Georgetown University Medical Center and MedStar Research Institute are as follows:

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third party payer (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, MedStar Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness.

PAYMENT FOR PARTICIPATION

You *will* be provided with a gift card for participating in this study. If you participate in the one time survey, you will be given a $10 gift card in appreciation of your time. You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study. Individuals who agree to further contact for the telephone follow-up survey will not receive any additional compensation for completing the telephone survey.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected nor will your relations with your physicians, other personnel and the hospital or university. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

By signing this form you do not lose any of your legal rights.

NEW FINDINGS

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under investigation in this study, and any information that may affect your interest in remaining in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Kristi D. Graves, Ph.D. at 202-687-1591 or the Division of Internal Medicine Resident on call 202-444-8168 (dial 0 to connect with the paging operator and ask for the Internal Medicine Resident on call). Be sure to inform the physician of your participation in this study.

For questions about your rights as a research participant, contact either of the following parties:

• The MedStar Research Institute - Georgetown University Oncology Institutional Review Board.

Address: Georgetown University Medical Center
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Telephone: 202-687-1506

• The Psychology Department Human Subjects Committee Chair - Virginia Tech Institutional Review Board.

Dave W. Harrison, Ph.D. Telephone: 540-231-4422 E-mail: dwh@vt.edu

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent _____ Print Name of Person _____ Date _____

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I am otherwise entitled. I agree to cooperate with (name of principal investigator) and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

Signature of Subject _____ Print Name of Subject _____ Date _____