MedStar Research Institute

MedStar Research Institute-Georgetown Oncology
Institutional Review Board

Date	February 22, 2010
To:	Kristi Graves, PhD Oncology 3300 Whitehaven ST NW, Suite 4100 Washington, DC 20007
From:	Nicole Jones Institutional Review Board
Title	An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in Colon Cancer Survivors
IRB#	2010-076
Annual Approval Date	January 27, 2010
Expiration Date:	January 26, 2011
Action	Expedited Initial Review Expedited Initial Review

Category 7b
HIPAA Waiver Application

Your above referenced protocol and consent form were approved through expedited review by Dr. Jimmy Hwang, the Chair of the Institutional Review Board or the designee on February 4, 2010. This is to inform you that you may commence your project. Please note that this approval is granted for a maximum of one year.

Any investigator whose project is externally funded must submit the applicable sponsor grant or contract for review and approval by the appropriate sponsored research office of the recipient institution [GU or MRI]. The project cannot proceed without the approval of the sponsored research office.

Approval for this study is through **January 26, 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 one month before the expiration date.***

The International Committee of Medical Journal Editors (ICMJE) has established a requirement for registration of clinical trials in a public registry prior to enrollment as a condition of consideration for publication. Georgetown University has established a central registration process through the National Library of Medicine's Clinical Trials Protocol Registration System ("PRS") known as ClinicalTrials.gov. Please contact the Georgetown University PRS administrator, Patricia Mazar, by e-mail at mazarp@georgetown.edu to set up a PRS user account to register clinical trials. The e-mail should contain the principal investigator's full name, department, phone number and e-mail address.

Additional information may be found at http://ora.georgetown.edu, http://clinicaltrials.gov/, and at http://www.icmje.org/clin_trialup.htm

For **all DoD sponsored research** please make note that you must obtain approval from the DoD human subjects committee as well as the local IRB approval before commencing research on this project.

**If promotional advertisements will be used for patient recruitment, they must be submitted for IRB review and approval prior to their use.
**Any incentives for participation in research are subject to IRB review and approval as well.

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 Research Institute and Georgetown University that reveals previously unknown risks from the procedures, drugs or devices used in this study.

Please refer to the above mentioned date and protocol number when making inquiries concerning this protocol.

26407
CC: PI, GUMC

CC: IRB file

8. ___ Continuing review of research previously approved by the convened IRB as follows:
   ___ (a) Where:
   (i) The research is permanently closed to the enrollment of new subjects, and
   (ii) All subjects have completed all research-related interventions, and
   (iii)The research remains active only for long-term follow-up of subjects, **OR**
   ___ (b) Where no subjects have been enrolled and no additional risks have been identified; **OR**
   ___ (c) Where the remaining research activities are limited to data analysis.

9. ___ Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories 2 through 8 do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Signature of Investigator — Date 1/19/10

Section Two: Additional Materials

Please attach the following materials to this application:

1. IRB Application form D-1
2. Informed consent form (if applicable)
3. Any survey tools or questionnaires

Section Three: FOR IRB USE ONLY

☒ Research Approved by Expedited Review (Category 7B) ☐ Expedited Review Not Allowed Signature of IRB Chair or Designee — Date 2/4/10	Comments:

* Note regarding categories 5 and 7: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See Form D-4 for more information.

Study Number: 10-076

Title: An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in Colon Cancer Survivors

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 ***"An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in Colon Cancer Survivors."*** 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.

Study Number: 10-076

Title: An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in Colon Cancer Survivors

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 30-45 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 Visa gift card.

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

Study Number: 10-076

Title: An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in Colon Cancer Survivors

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

IRB Approval Stamp
MedStar Research Institute-Georgetown University
Oncology Institutional Review Board

Approved FEB - 4 2010 (Date)

Expiration JAN 26 2011 (Date)

10-076

APPLICATION FOR WAIVER (OR ALTERATION) OF HIPAA AUTHORIZATION FOR RESEARCH PURPOSES

NOTE: Please complete each section in its entirety. If you feel that a question, section or the potential selections below are not applicable to your situation, you MUST explain why IN DETAIL on the form and in the cover memo that accompanies your submission. Failure to do so may result in this application being delayed or rejected.

Contact Information for Investigator:

Date: January 26, 2010

Applicant: Dr. Kristi Graves **Telephone Number:** (202) 687-1591 **e-mail:** kdg9@georgetown.edu

Institutional Affiliation: MedStar Corporate Office

Project Title: ***An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in Colon Cancer Survivors.***

IRB Application Number (if known) _____

Purpose of Application (select all that apply):

☒ **Partial Waiver of Authorization**
- ☒ *To screen medical records, operational databases and systems (i.e. lab systems), or appointment logs (i.e. surgical schedules), admissions logs, etc. to identify potentially eligible research participants.*
- ☒ *For recruitment to contact potential participants in order to obtain their Authorization.*

☐ **Full Waiver of Authorization**
(For use when it is impractical or impossible to obtain a person's written Authorization)

☐ **Alteration of Authorization Requirements**
(For use when the form or core components of the form are a barrier to obtaining Authorization)

Purpose of the Study: Please provide a brief summary of what is being investigated by this study:

Prior work has documented the positive impact of diet and physical activity on the improvement of health-related outcomes in cancer survivors. The present study aims to build upon this prior research by examining the non-medical related outcomes for colorectal cancer survivors at high risk for a recurrent diagnosis. Although previous research has investigated health behaviors of various cancer survivor populations, previous research has largely failed to examine predictors of health behavior change among cancer survivors who are at increased risk due to their personal and family cancer history. Therefore, the purpose of the present study is to fill this gap in the research by exploring potential predictors of lifestyle changes, specifically diet and physical activity, in a sample of colorectal cancer survivors who are at high risk of developing a second colorectal cancer.

Waiver/Alteration Application Criteria

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Waiver/Alteration Application Criteria

IRB Checklist	***Investigators Questionnaire***
	For each subpart below, the IRB must agree that the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on the responses below.
HIPAA Applicability	**1) Will you be accessing, using, receiving, or disclosing any health information relating to any individual that includes any PHI identifiers (described in instructions above)?**
	☒ Yes. HIPAA applies and this form may be required. ☐ No. STOP - HIPAA is not applicable you need not fill out this form.

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Necessity of Waiver	2) Could the proposed research practicably be conducted without the waiver or alteration of Authorization?
☐ IRB must agree that that it is truly impractical (not just inconvenient) for the researcher to obtain written Authorization from the research participants. Waiver of Authorization is not appropriate if Informed Consent is to be obtained.	☐ **Yes.** STOP – the study is not eligible for a waiver or alteration of Authorization. ☒ **No.** Please describe why it would be impossible or impractical to obtain each subject's Authorization for use and/or disclosure their health information using the standard written form of HIPAA Authorization: We are applying for a partial waiver of authorization. Specifically, we will be working with staff members of both the Familial Cancer Registry (FCR) and Clinical Genetics Program to screen a cancer registry database and clinical genetic counseling lists to identify potentially eligible research participants. After IRB approval at Georgetown University (GU) and Virginia Tech (VT), clinical and registry staff will send letters of invitation to participate in the study to identified eligible participants. No identifying information will be turned over to the GU or VT researchers until potential participants have agreed to be contacted to learn more about the present study. These steps will allow us to contact potential participants in order to then obtain their Authorization and consent to participate in the study.
Necessity of PHI	**3) Could the proposed research-related activity practicably be conducted without the access, use or disclosure of Protected Health Information (PHI)?**
☐ IRB must agree that that PHI is necessary (not just preferred) for the proposed research activity.	☐ **Yes.** STOP – the study is not eligible for a waiver or alteration of Authorization. ☒ **No.** Please explain why PHI is necessary for the proposed research-related activity: We will be working closely with the staff of the Familial Cancer Registry (FCR) and Clinical Genetics Program so that we can send letters to potential participants informing them about the study. Letters will be sent from the FCR staff or the patients' genetic counselor and will include mechanisms (decliner post card and a toll-free telephone number) for patients to decline further contact about the study. Eligible clinical patients who do not decline will then be approached by a Georgetown University Cancer Control research assistant via telephone in order to obtain verbal consent to share their contact information with the collaborating researcher. Following letter notification, eligible FCR patients will be approached by an FCR staff member via telephone. At that time, eligible Clinical and FCR patients will be informed about the study and will be given the option to decline further contact. For individuals who do not decline further contact by study investigators (including collaborators), their contact information will be shared with the collaborating VT researchers. The collaborating VT researchers will then contact eligible individuals directly. Individuals will be invited to participate and interested individuals will provide verbal consent, followed by written informed consent, and will also sign a HIPAA authorization. We cannot assist FCR and Clinical Program staff with the review of the registry database or genetic counseling lists to determine patients' eligibility to participate without having access to patients' **names, dates of birth, addresses, and telephone numbers**. Thus, without this partial waiver, we would be unable to contact eligible patients in advance so that they may have the option to decline the study and not be approached by a member of the study team.

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Scope of PHI Requested ☐ IRB must consider whether the scope of PHI requested is appropriate for the proposed research-related activity. (i.e. only contact information may be needed for recruitment)	**4) Is the PHI to be accessed, used or disclosed the minimum necessary to accomplish the research objectives described in this Waiver request?** ☒ **Yes.** Please describe the specific PHI elements needed for the research-related purposes giving rise to this Waiver request. We are applying for this waiver to review a cancer registry database and clinical genetic counseling lists to access patient names, addresses, birthdates, date(s) of service, and telephone numbers. ☐ **No.** STOP. The IRB may not approve your Waiver request.
Sources of Protected Health Information?	**5) Please identify the facility location(s) where PHI will be accessed or obtained?** Georgetown University Medical Center – The Familial Cancer Registry and Clinical Genetics Program located within the Cancer Control Program of the Lombardi Comprehensive Cancer Center.
	6) What are the anticipated sources of PHI? *(Choose all that apply)* ☒ Physician records ☐ Hospital records ☐ Billing system records ☐ Laboratory results ☐ Pathology results ☐ Radiology results ☐ Mental Health Records (may requires specific approvals) ☐ Interviews/surveys/questionnaires ☐ Databases or tissue repositories that were created for operational (i.e. non-research) purposes
	☒ Tissue samples, research repositories previously collected for research purposes. If yes, was research data and/or samples collected pursuant to: 1) An IRB approved protocol? ☒ Yes ☐ No 2) Informed Consent? ☒ Yes ☐ No 3) Waiver of Informed Consent? ☐ Yes ☒ No 4) HIPAA Authorization? ☒ Yes ☐ No 5) Waiver of Authorization? ☐ Yes ☒ No

Access to and Collection of PHI	7) Describe how PHI is to be accessed or obtained for the purposes of this Waiver request?
☐ IRB must consider whether direct access to records or databases would adversely affect the rights and interests of individuals and/or exceeds the minimum necessary requirements of HIPAA	☐ Direct access to Covered Entity's paper-based medical records ☐ Direct access to Covered Entity's electronic medical records (or Azyxxi) ☐ Direct access to Covered Entity's operational databases (laboratory, billing, etc.) ☐ Direct access to research database ☒ Receipt of reports/data from Physicians or the Covered Entity ☐ Other (please explain)
	8) Identify who on the research team will control access to the PHI obtained as a result of the Waiver of Authorization? (If PHI will be accessed for the purpose of this waiver request but will not be in any way recorded or stored (e.g a database is viewed but no identifiers are recorded), please indicate "N/A – No PHI will be recorded or stored".)
☐ IRB must consider whether there is an adequate plan to limit access based on the needs of the research-related activity.	A study co-investigator, who has completed Human Subjects Training and HIPAA training, will be the primary study team member to collect PHI. The PI and second co-investigator will also have access to the PHI for study oversight and quality control purposes.
Recruitment Plan and Plans for Using PHI	**9) Describe how the PHI obtained will be used in identifying and recruiting research participants or in conducting the study or for any other purpose?**
☐ IRB must agree that recruitment plan/use of PHI is consistent with the plan described in the research protocol and protects the interests of potential research participants as well as the interests of those who may not wish to participate.	*(Choose all that apply)* ☐ To screen medical records or operational databases to identify potentially eligible research participants. ☐ To contact treating providers and obtain their permission to contact potential participants in order to obtain their Authorization (please attach proposed Authorization). ☒ To contact potential participants directly in order to obtain their Authorization [redacted]. ☒ Treating Physicians will provide a list or otherwise identify potentially eligible research participants. ☐ PHI obtained will be used to conduct the entire research project (i.e. chart reviews) and no individuals will be contacted. ☐ Other (please describe):
	10) Describe who will make initial contact with potential research participants and how?
	(Choose all that apply) ☒ Telephone contact ☒ By Investigator or Research Coordinator ☐ By Treating Physician or their staff ☒ Letter, e-mail or other written correspondence ☐ Not applicable – No research participants will be contacted ☐ Other (please describe)

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Re-use or Disclosure of PHI to Third Parties	**11) For the period during the study and afterwards, please identify who else will or is likely to receive or view PHI obtained pursuant to the Waiver of Authorization and for what purpose? (Please note: This includes the disclosure of screening logs to the study sponsor if such logs include any identifiers including dates.)**
☐ IRB must determine that the re-use or disclosure of PHI to third parties is permitted because it is ▪ Required by law, ▪ For authorized oversight of the research study, or ▪ For other research purposes permitted under HIPAA	*(Choose all that apply)* ☐ Other investigators (please identify) (describe purpose) ☐ Study sponsor (please identify) (describe purpose) ☐ CRO (please identify) (describe purpose) ☐ Study monitor(s) (i.e. DSMBs) (please identify) ☐ Government oversight agencies (FDA, OHRP, etc.) (describe purpose) ☐ Other (please explain)
Data Security and Plans to Protect Identifiers	**12) Describe the plan to protect identifiers received (i.e. those identified above) from improper *uses.*** *(Choose all that apply)* ☐ Only de-identified data will be released by the Covered Entity and retained by the research staff. ☐ Only a limited data set will be released by the Covered Entity and retained by the research staff. ☒ Only coded information will be used in connection with the research study (Please Note: Under HIPAA regulations the code may not be based upon any element of any of the 18 HIPAA identifiers (e.g. patient initials, a permutation of the patient's social security number, etc.) ☒ All research team members will sign Confidentiality statements agreeing not to use or disclose PHI except as permitted as part of their duties. ☐ PHI will be released by the Covered Entity only to a MedStar Workforce member who is permitted to use the PHI for operational purposes ☐ PHI will be released by the Covered Entity only to recipients who have a MedStar Health-approved Business Associate Agreement and who have agreed to protect the PHI. (Please attach a copy of the Business Associate Agreement.) ☐ Other (please explain):
	13) Describe the plan to protect identifiers received (i.e. those identified above) from improper *disclosures.* *(Choose all that apply)* ☒ Electronic PHI will be stored on a secure network ☐ Electronic PHI will be encrypted ☒ Electronic PHI will be password protected ☒ Paper-based PHI will be secured in a locked office ☒ Paper-based PHI will be secured in a locked cabinet ☐ All PHI will be de-identified (with all identifiers properly destroyed) ☒ All PHI will be coded by Investigator with re-identification link securely stored in a separate location. ☐ Other (please explain)

Plan to Destroy Identifiers	**14) Will all PHI elements received (i.e. those identified above) be destroyed at the earliest possible opportunity? *Identifiers obtained via Waiver of Authorization must be destroyed at the earliest possible opportunity unless there is a health or research justification for retaining the identifier (or such retention is otherwise required by law).***
☐ IRB must determine that the PHI is to be destroyed at the earliest possible time.	☒ **Yes.** a) Materials containing PHI such as screening logs will be destroyed upon completion of: ☐ Recruitment attempt without enrollment ☐ Enrollment in the study ☐ Chart Review/Data Analysis ☒ Subject participation and record-keeping requirements ☐ FDA-approval or end of record-keeping requirements ☐ Specimen Processing ☐ Other (please explain) b) Who will destroy the identifiers (Name the specific person(s) and titles). Study co-investigator(s) and/or Principal Investigator c) How will the identifiers be destroyed? (Placing identifiers in trash is not an acceptable method for disposing of identifiers). Identifiers will be shredded. ☐ **No.** Justify the need for retaining the identifiers. (Choose One)
Alteration of Authorization Requests	**15) If alteration of the standard HIPAA Authorization form (instead of a Waiver) is requested, explain why and how the form of Authorization would be altered and attach the proposed altered Authorization that you proposed to use.**
	N/A
Minimal Risk to Privacy	**16) Explain why the proposed research-related activity (or the alteration) presents no more than a "minimal risk" to privacy[1]:** Prior to any sharing of existing data and PHI with study investigators, all eligible individuals will have been informed about their option to decline further contact through return of a stamped decliner postcard, a toll-free telephone number, or via telephone contact with an internal staff member. Furthermore, no PHI (i.e., contact information) will be shared with study investigators until verbal consent is provided by eligible individuals.

[1] "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

10-076

INVESTIGATOR'S ASSURANCES:

I certify and agree that the above statements and representations are truthful and accurate. I further agree that I will not reuse the protected health information ("PHI") for which I have requested this Waiver or Alteration of HIPAA Authorization (i.e., use other than as described in this application form) or disclose the PHI to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB. I also assure the IRB that the PHI for which I have requested this waiver or alteration is the minimum amount of PHI necessary for the research purpose described in this application. I understand that any misrepresentations may result in disciplinary actions, loss of privileges, reporting to licensure boards, and/or other sanctions.

Signature of Investigator **Date** 1/19/10

IRB Stamp

FEB - 4 2010

INSTITUTIONAL REVIEW BOARD

MEDSTAR RESEARCH INSTITUTE AND
GEORGETOWN UNIVERSITY MEDICAL CENTER
INSTITUTIONAL REVIEW BOARDS

10-076

[IRB #_____ "An Exploration of Social Cognitive and Psychosocial Predictors of Health Behavior Change in High-Risk Colon Cancer Survivors"
Kristi D. Graves

Statement of Approval/Denial of Waiver/Alteration of Authorization

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permit you to use or disclose to an investigator, patient information pursuant to documentation of waiver/alteration of patient Authorization by the investigator's Institutional Review Board (IRB) (45 C.F.R. § 164.512(i)). This Statement satisfies the HIPAA requirement for documentation that the IRB has reviewed the waiver/alteration request in accord with the requirements of Federal human subject protection regulations and, having determined that the criteria set forth at 45 C.F.R. § 164.512(i)(2)(ii) have been met and have been approved as follows:

Purpose of the Waiver. This statement certifies that the IRB named below approved a request to [*waive/alter*] the HIPAA Authorization requirement to permit the use or disclosure of patient protected health information (PHI) to the investigator named above for purposes of:

- ☐ *Partial Waiver.* For screening or identifying prospective research participants.
- ☐ *Partial Waiver.* For contacting or recruiting prospective research participants.
- ☐ *Full Waiver.* Conducting the entire study named above without Authorization.
- ☐ Alteration of the Authorization requirement as follows (Describe nature of alteration):_____

PHI Permitted to Be Released. In approving the waiver/alteration the Board has determined that access/use by the investigator named above to/of the following information is necessary for the research activity and that the investigator is permitted to use/disclose the following:

- ☐ All information described in the Investigator's Request for Waiver or Alteration of HIPAA Authorization for Research; ***OR***
- ☐ The following information: _____

The scope of the Board's *Waiver/Alteration to* Authorization is limited solely to this information. Please contact the MedStar Research Institute Office of Research Integrity (ORI) at 301-560-7339 should you have any questions regarding this statement.

Institutional Review Board Action (For IRB Use Only)

- ☑ **Approved**
  - ☑ **Via Expedited Review by IRB Chair (or Designee) On:** 2/4/2010
  - ☐ **Via Full IRB Committee On:**_____
- ☐ **Not Approved**
  - ☐ **Via Expedited Review by IRB Chair (or Designee) On:** _____
  - ☐ **Via Full IRB Committee On:**_____
- ☐ **Approval Deferred Pending the Following Actions:**_____

Signature of IRB Chair (or Designee) **Dated** 2/4/2010

Covered Entity Tracking Data *Date of Initial Disclosure:*_____

Recipient and Contact Information:_____

Description of Patient Information Disclosed:_____

Georgetown University

IRB Stamp
FEB - 4 2010
INSTITUTIONAL REVIEW BOARD

RESEARCH AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

10-076

Who may have and use my health information?

I agree to allow **Kristi D. Graves, Ph.D., Richard 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 Participant's Personal Representative)* _____

Representative's authority to sign for Participant, *(parent, guardian, power of attorney for healthcare, etc.)* _____