



**TITLE OF PROJECT:**  
**Stamford Hospital Familial Colorectal Cancer Registry**

**INVESTIGATOR:**  
**Dr. McClane**  
**70 Mill River Street**  
**Stamford, CT 06902**

Dear Sir/Madam:

We would like to invite you to join the Stamford Hospital Familial Colorectal Cancer Registry. We are asking you to join because either you or your physician indicated that you may be interested in participating. Individuals who are eligible to join may have a personal or family history of certain types of cancer or related conditions. Before you agree to participate, we ask that you read this letter carefully and call us if you have any questions.

**PURPOSE OF THE REGISTRY:**

The Stamford Hospital Registry is a community and professional resource whose vision is to decrease the death rate of colorectal cancer and associated medical problems. The registry is a voluntary database that contains general, medical, and family history information. By collecting information from many families, we hope to learn more about why colorectal cancer develops and how to prevent it.

The purpose of establishing a colorectal cancer registry at Stamford Hospital is to reduce the death rate of colorectal cancer by promoting knowledge of the risks and implications of a family history of colorectal cancer, and by conducting pertinent research in a variety of areas associated with colorectal cancer.

**DESCRIPTION OF THE REGISTRY**

Participants will be enrolled in the registry based on eligibility and interest. Enrollment will be ongoing and there will be an estimated 50 participants per year.

Your participation in the registry will require approximately one hour of your time on one occasion.

If you agree to join the registry, we will ask to you do the following things:

1. Read, sign, initial the bottom of each page and return this CONSENT FORM (all 4 pages).

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Participant's initials: \_\_\_\_\_

2. Complete and return the enclosed QUESTIONNAIRE. This questionnaire includes cancer-related health questions about you and your family.

3. Forward any pathology reports or genetic test reports to our office, where possible.
4. Agree that we may use your information for research purposes. The records of this registry will be kept confidential and any data used for research will be de-identified (that is, used anonymously).

We will ask you to consider to:

5. Agree that we may contact you in the future to update your information and / or ask whether you would like to participate in future research related to the registry. Participation in this research would be voluntary.

**POTENTIAL RISK AND DISCOMFORTS:**

As a member of the registry, you may expect to receive information about colorectal cancer, the importance of screening, and how family history affects the risk of developing colorectal or other cancers. We may give you information about genetic counseling and how it may benefit you. Learning about cancer risk could cause anxiety and lead to psychological distress for you and / or your family members.

**POTENTIAL BENEFITS:**

You will not benefit personally from participating in the colorectal cancer registry. Participation in this registry may help health care professionals gain a better understanding of factors related to colorectal cancer.

**ALTERNATIVES TO PARTICIPANTS:**

Participation in the registry is voluntary. It will not affect your medical care or your opportunity to have genetic counseling if you choose not to participate. You may receive genetic counseling whether or not you choose to join the registry.

**CONFIDENTIALITY:**

Confidentiality of your records will be maintained. Only personnel directly involved in the registry will have access to the records. All information and research records will be stored in a locked office and on a secure computer. You may request that we provide copies of your information to third parties, such as physicians, genetic counselors, or family members, but we will not do so without your permission. Every effort will be made to maintain this level of confidentiality to the extent required by federal and state law.

Stamford Hospital is required by law to protect your health information. You are being asked to authorize the use of your personal health information collected as well as your past medical history collected as part of the registry. By signing this document, you authorize Stamford Hospital to use your health information for this purpose and/or disclose (release) your health information for this purpose.

Persons/groups of persons listed in this document who receive your health information **may** not be required by Federal privacy laws to protect it and may share your information with others without your permission

You may change your mind and revoke this Authorization at any time, but you must do so in writing. However, information already collected may continue to be used if needed to protect the integrity of the registry. To revoke this Authorization, you must write to: Vicki Lyus at Stamford Hospital, 30 Shelburne Road, Stamford, CT 06902. Once you have signed this Authorization, there is no expiration date. Your Authorization remains valid unless you choose to revoke it.

**COSTS/REIMBURSEMENTS:**

There are no costs associated with being a part of the colorectal cancer registry or research based on the registry program.

**VOLUNTARY PARTICIPATION:**

Participation in this registry is voluntary. If you decide not to participate, this will not affect your present care or your ability to receive future medical care or genetic counseling at Stamford Hospital, or to receive any benefits to which you are otherwise entitled.

A signed copy of this consent form will be given to you.

**TERMINATION OF PARTICIPATION:**

You may choose to end your participation in this registry at any time. If you do choose to end your participation in this registry, it will have no effect on the medical care provided to you, or the opportunity to receive genetic counseling.

**CONTACT PERSON:**

The Cancer Genetics Program at Stamford Hospital currently supports the registry. If you have any questions about your participation in the registry, please contact:

Vicki Lyus, M.S.  
Genetic Counselor and Registry Coordinator  
Cancer Genetics Program, Stamford Hospital  
30 Shelburne Road, Stamford, CT 06902  
(203) 276-7693  
[vlyus@stamhealth.org](mailto:vlyus@stamhealth.org)

Thank you for taking the time to consider participating in the registry. If you agree to join the registry, please sign the signature page, initial each page at the bottom right, and return this entire form including the signature page and the enclosed questionnaire. We look forward to your participation.

## Authorization and Consent for Participation

### Registry Participant:

I have read this consent document. The cancer registry information has been explained to me and all my questions have been answered. My consent to participate in this registry has been given freely and willingly. I authorize the use of my personal health information as described in this form.

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Printed Name of Participant

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Signature of Participant

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Date

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*OPTIONAL: If you agree to be contacted in future, for the purpose of updating the registry information or being invited to participate in research protocols that may evolve from the registry, please sign below:*

I agree to be contacted in future for purposes of updating the registry information and being invited to join future research protocols:

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Printed Name of Participant

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Signature of Participant

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Date

### Investigator:

I have reviewed the information in this consent form with the subject and have answered any questions the subject has asked regarding the registry to the best of my ability.

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Investigator/Individual

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Signature of Investigator

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Date



**REPRODUCTIVE HISTORY – WOMEN ONLY**

**How old were you when you had your first menstrual period?** \_\_\_\_\_

**Are (were) your periods regular?** Yes / No

**Have you taken birth control pills?** Yes / No

If yes, when? From age: \_\_\_\_\_ To age: \_\_\_\_\_

From age: \_\_\_\_\_ To age: \_\_\_\_\_

**Do you still menstruate regularly?** Yes / No

**Age at menopause:** \_\_\_\_\_

**What was the reason your periods stopped (if they have) ?**

- Natural menopause (change of life)
- Oophorectomy (removal of ovaries)
- Hysterectomy (removal of uterus)
- Chemotherapy which stopped periods
- Other: \_\_\_\_\_

**Have you ever taken Hormone Replacement Therapy?** Yes / No

If yes, when: From age: \_\_\_\_\_ To age: \_\_\_\_\_

From age: \_\_\_\_\_ To age: \_\_\_\_\_

**Please list any other hormones you have taken:** \_\_\_\_\_

**Have you ever been pregnant?** Yes / No **If applicable, age at 1<sup>st</sup> delivery** \_\_\_\_\_

**Number of pregnancies (please include all conceptions) in total:** \_\_\_\_\_

**Have you ever had IVF or taken fertility drugs to become pregnant?** Yes / No

If yes please explain: \_\_\_\_\_

**DIET (MEN & WOMEN)**

Please approximate, to the best of your knowledge.

How many servings of dairy products do you eat each day? 0 1 2 3 4 5 6 7+

How many servings of fruits and vegetables do you eat each day? 0 1 2 3 4 5 6 7+

How many servings of grains do you eat each day? 0 1 2 3 4 5 6 7+

How many servings of meat / equivalents do you eat each day? 0 1 2 3 4 5 6 7+

How often do you eat red meat? Never / 1-2 times per month / 1-2 times per week / 3+ times per week

How often do you eat high fat foods? Never / 1-2 times per month / 1-2 times per week / 3+ times per week

**Do you have concerns about your weight?** Yes / No

If yes, please specify: \_\_\_\_\_

**If yes, have you been diagnosed as clinically obese?** Yes / No

**CURRENT SURVEILLANCE:**

Please indicate which of the following health screening tests you receive.

Screening	Please check all that apply	Age started	Frequency	Date last performed
Gyn & Pap exam	<input type="checkbox"/>			
Vaginal Ultrasound	<input type="checkbox"/>			
Blood test Ca-125	<input type="checkbox"/>			
Sigmoidoscopy	<input type="checkbox"/>			
Colonoscopy	<input type="checkbox"/>			
Barium Enema	<input type="checkbox"/>			
Fecal Occult Blood Test	<input type="checkbox"/>			
Prostate Specific Antigen	<input type="checkbox"/>			
Digital Rectal Exam	<input type="checkbox"/>			

**Have any of these test results been abnormal?** Yes / No

If yes, please specify: \_\_\_\_\_

**PERSONAL MEDICAL HISTORY**

**Have you been diagnosed with cancer of the colon or rectum?** Yes / No

**If yes, at what age were you diagnosed?** \_\_\_\_\_

**Where was the tumor?** \_\_\_\_\_

**How was your cancer diagnosed?** \_\_\_\_\_

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**Did you have surgery?** Yes / No

If yes, which surgery did you have?

- Part of colon removed
- Entire colon removed
- Polyps removed only
- Other (please specify) \_\_\_\_\_

**Please indicate what the pathology was (if known):** \_\_\_\_\_

**Did you have any polyps?** Yes / No      **If yes, how many polyps?** \_\_\_\_\_

**Did you have chemotherapy?** Yes / No      **If yes, what regime (if known)?** \_\_\_\_\_

**Did you receive radiation therapy?** Yes / No      **If yes, for how long (if known)?** \_\_\_\_\_

**Did you have a recurrence?** Yes / No      **If yes when & where:** \_\_\_\_\_

**Name and address of physician who treated you for colorectal cancer (if applicable):** \_\_\_\_\_

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**May we contact your doctor to obtain the pathology reports?** Yes / No

**Have you been diagnosed with any other types of cancer?** Yes / No

**If yes, what types of cancer(s) and at what age were you diagnosed?** \_\_\_\_\_

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**Have you had additional colorectal polyps?**

Yes / No

If yes, how many polyps have you had in your lifetime? 1 2 3 4 5 6-15 16-50 51-100 100+ (Please circle)

Age at first polyp: \_\_\_\_\_ Please indicate the type of polyps (if known): \_\_\_\_\_

**Do any of your family members have colorectal polyps?**

Yes / No

If yes, which family member? \_\_\_\_\_ How many polyps? \_\_\_\_\_

**Do you have Inflammatory Bowel Disease? (Ulcerative colitis, Crohn's disease)** Yes / No

If yes, at what age was it diagnosed? \_\_\_\_\_ What is your diagnosis? \_\_\_\_\_

**Do you have a family member with Inflammatory Bowel disease?**

Yes / No

If yes, which family member? \_\_\_\_\_ What is their diagnosis? \_\_\_\_\_

**Do you have any of the following** (please check ALL that apply):

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Fibrocystic breast disease | <input type="checkbox"/> Skin alterations          | <input type="checkbox"/> Osteoporosis        |
| <input type="checkbox"/> Endometriosis              | <input type="checkbox"/> Macrocephaly (large head) | <input type="checkbox"/> Heart Disease       |
| <input type="checkbox"/> Uterine Fibroids           | <input type="checkbox"/> Extra / Missing teeth     | <input type="checkbox"/> Ovarian cysts       |
| <input type="checkbox"/> Lipomas (fatty lumps)      | <input type="checkbox"/> Hyperthyroidism           | <input type="checkbox"/> High cholesterol    |
| <input type="checkbox"/> Fibromas                   | <input type="checkbox"/> Hypothyroidism            | <input type="checkbox"/> High Blood pressure |

**Do you have any other health problems?** \_\_\_\_\_

**Please list any medications you are taking:** \_\_\_\_\_

**Please check which of the following you take regularly (if any):**

- |                                    |                                       |                                    |
|------------------------------------|---------------------------------------|------------------------------------|
| <input type="checkbox"/> Vitamin C | <input type="checkbox"/> Aspirin      | <input type="checkbox"/> Vitamin E |
| <input type="checkbox"/> Vitamin D | <input type="checkbox"/> Folic Acid   | <input type="checkbox"/> Ibuprofen |
| <input type="checkbox"/> Calcium   | <input type="checkbox"/> Multivitamin |                                    |

**FAMILY HISTORY**

Information regarding family history is very important for our evaluation of your family.

Please complete as much information as possible. “**Siblings**” refers to **brothers and sisters**.

Family Member First Name	Living / Deceased	Age or age at death	Cause of death	Cancer Type (colon, breast, etc.) If none, write none	Age of cancer diagnosis
Your Spouse  _____					
Mother:  _____					
Father:  _____					
Your children:  1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____					
Your brothers & sisters (same mother & father)  1. _____ 2. _____ 3. _____ 4. _____ 5. _____					

Family Member First Name	Living / Deceased	Age or age at death	Cause of death	Cancer Type (colon, breast etc) If none: write none	Age of cancer diagnosis
Brothers & Sisters <i>(different father)</i>  1. _____ 2. _____					
Brothers & Sisters <i>(different mother)</i>  1 _____ 2. _____					
Your Mother's Mother: _____					
Your Mother's Father: _____					
Your Father's Mother _____					
Your Father's Father: _____					
Mother's siblings:  1. _____ 2. _____ 3. _____ 4. _____					

Family Member First Name	Living / Deceased	Age or age at death	Cause of death	Cancer Type (colon, breast etc) If none: write none	Age of cancer diagnosis
Father's siblings:  1. _____  2. _____  3. _____  4. _____					
Nieces / Nephews: (children of your siblings)  1. _____. <i>Child of:</i>  2. _____. <i>Child of:</i>  3. _____. <i>Child of:</i>  4. _____. <i>Child of:</i>  5. _____. <i>Child of:</i>  6. _____. <i>Child of:</i>					

Please list any additional relatives who have been diagnosed with cancer, with the type of cancer and approximate age of diagnosis: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**GENETIC TESTING**

**Do you or does any family member have a genetic condition?** Yes / No

If yes, please indicate which condition:

\_\_\_Familial Polyposis (FAP)

\_\_\_Hereditary nonpolyposis colorectal cancer (HNPCC)

\_\_\_Juvenile polyposis (JPC)

\_\_\_Hereditary Mixed Polyposis

\_\_\_Other genetic condition: \_\_\_\_\_

Please indicate who in the family has the genetic condition. \_\_\_\_\_

**Have you had genetic testing?** Yes / No

If yes, what type of testing did you have? \_\_\_\_\_

What were the results of the testing? \_\_\_\_\_

Where and when did the testing take place? \_\_\_\_\_

**Did you receive genetic counseling?** Yes / No

**Would you like to have genetic counseling with/without genetic testing?** Yes / No

If yes, would you like us to contact you to arrange this? Yes / No

Do you have any further comments?

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Thank you for taking the time to complete this questionnaire. Your time is really appreciated.

Please return the completed questionnaire to:

Vicki Lyus, MS in the enclosed stamped address envelope.

## **FOOD DEFINITIONS**

### **Dairy**

One serving is:

1 cup of milk

1 cup of yogurt

1-1/2 ounces of natural cheese

2 ounces of processed cheese

1/2 cup of ricotta cheese

2 cups of cottage cheese.

### **Fruit / Vegetables**

One serving is:

1 cup of raw leafy vegetables

1/2 cup of chopped or cooked vegetables/ fruit

1 ounce of vegetable chips

3/4 cup of fruit/vegetable juice

1 whole fruit such as a medium apple, banana, or orange; a grapefruit half

1/4 cup of dried fruit

### **Grains**

One serving is:

1 slice of bread

1 small roll

1/2 bagel

1 muffin or croissant

1 ounce of ready-to-eat cereal

1/2 cup cooked cereal, rice, or pasta

### **Meat / Meat Equivalents**

One serving is:

Three eggs, 1.5 cup of tofu, 6 tablespoons of peanut butter, 1 cup of nuts, and 3/4 cup of seeds, 3 oz lean meat e.g. one burger

### **Higher Fat Foods**

Cream, butter, margarine, cream cheese, oil, lard, meat drippings, cocoa, and chocolate and fat excess fat from meat, dairy or grains.