

HOWARD UNIVERSITY

Office of Regulatory Research Compliance

Date: March 31, 2014

To: Adeyinka O. Laiyemo, M.D., M.P.H.
Department of Medicine

From: The Office of Regulatory Research Compliance

Title: **IRB-14-MED-11:** Using Patients' Social Contact to Improve Out-Patient Endoscopy Among Blacks

Approval Date: **March 28, 2014**

Expiration Date: **March 27, 2015**

Action: Expedited Review- *New Faculty Research*

The above-referenced submission was approved by expedited review on March 28, 2014. Approval for this study is through **March 27, 2015**.

Please be reminded of the following:

1. It is your responsibility to ensure that a continuing review report is submitted to the IRB in a timely manner. Should you anticipate renewing this protocol at the end of the approved time frame, please submit the C-2 Form **60 days prior to the expiration date** (Please note that this office will automatically terminate the project on the date stated above, unless reviewed and re-approved by the IRB.);
2. If you plan to close this protocol, a close-out report must be submitted to the IRB within 30 days after completion. Use an C-2 Form for this purpose as well; and
3. During the project period of this research, the IRB has the right to conduct a monitoring site visit and you will be given prior notice.
4. IRB date-stamped consent documents should be used when obtaining informed consent;
5. All informed consent documents must be kept on record with this project and should be archived by you for at least three (3) years after the last date of the IRB approval; and
6. Any changes including changes in personnel, modifications to the protocol and advertising must be reviewed and approved by the IRB prior to initiation.
7. The HU IRB Federal Wide Assurance number is FWA00000891.

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

CC: IRB File

Thomas O. Obisesan, M.D., MPH, F.A.A.F.P., AVP of Regulatory Research Compliance



**CONSENT FOR INVESTIGATIVE PROCEDURES
HOWARD UNIVERSITY CANCER CENTER
WASHINGTON, DC 20060**

GASTROENTEROLOGY CLINIC

Title: Using Patients' Social Contact to Improve Out-Patient Endoscopy among blacks (Upper Endoscopy)

Principal Investigator: Adeyinka O. Laiyemo, MD, MPH

Tests and/or procedures to be performed

Participating in this study is voluntary. Your refusal to participate will not affect your care by your doctor. However, if you agree to participate, you will be asked to complete an intake form, complete the Lubben Social Network Scale (LSNS-6 version), and give permission for us to obtain and review your endoscopy reports.

Why is this study being done?

Approximately one out of every ten deaths in the United States is attributable to an underlying disease of the gastrointestinal system. Endoscopy is used to diagnose and treat these diseases such as peptic ulcer disease and Helicobacter Pylori infection. Unfortunately, a high rate of non-compliance to out-patient endoscopy has been reported among blacks.

This study is being done to find out if engaging a patient's social contact that the patient chooses by himself or herself can improve endoscopy services delivery to blacks. This information can be used to design healthcare delivery to blacks, and hopefully, will lead to increased use of endoscopy to improve the health of underserved people.

Who is doing this study?

The Principal Investigator for this study is Adeyinka O. Laiyemo, MD, MPH at the Howard University Cancer Center. He is a gastroenterologist and cancer prevention expert who was trained at Howard University and the National Institutes of Health (NIH).

Procedures: What is involved in this study?

If you agree to participate in this study the following will happen:

1. You will be asked to sign this consent form that you agree to participate in this study.
2. Then, you will be asked to complete an intake form about yourself and your health.
3. You will also be asked to complete Lubben Social Network Scale (LSNS-6 version)

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4. You will be asked to choose 2 social contacts (persons who you are familiar with such as family members or friends) who could be engaged by our research team to assist you in completing your upper endoscopy. We will talk to the first contact person you chose, but if the person could not be reached or is not able to participate in the study, we will call the second person you chose.
5. There will be 2 groups of participants in this study. In one group, we will engage the social contact the participant has chosen by explaining to him or her to assist the participant in the process of completing the scheduled endoscopy that the doctor recommended. We will only discuss the process involved in completing an upper endoscopy. We will not discuss the medical history of the participant with the social contact under any circumstance. We will not engage the social contact in the second group. You will be randomly assigned to group 1 or group 2.
6. We will call you to remind you of your upper endoscopy appointment within one week of your test. If we engaged your social contact, we will also contact him or her to give a reminder about your test.
7. We will check whether you came for your upper endoscopy appointment and completed the test. We will request your endoscopy report from the doctor who performed your test.
8. The information from this study will be recorded on paper and later transferred to computer recording.
9. Your information will be confidential and information that can identify you such as your name, address etc will not be analyzed and will not be reported when the result of the study is published. Once the study is completed, all identifying information will be removed completely.

How many people will be involved in the study?

There will be 200 people participating in this study.

How much time would you spend to be part of this study?

We estimate that you will spend 15 minutes in total (10 minutes to complete the intake form and Lubben Social Network Scale and 5 minutes for the reminder phone call before your test).

What are the risks of the study?

The risk of participating in this study is minimal. The things you will be doing have no more risk of harm than you would experience in everyday life. If you find any of the questions we ask you to be upsetting or stressful, you may choose not to answer that question. Also, we can provide you with referrals to resources to help you with those feelings. We can provide referrals to the Howard University Department of Psychiatry if needed. Care will be given at the usual charge to you.

We will protect your privacy and protect your health information. We will not discuss your medical history with your social contact under any circumstance.

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Are there benefits to taking part in the study?

You may receive a direct benefit by taking part in the study through completing the upper endoscopy that your doctor recommended for you. Your social contact may also gain more knowledge about endoscopy as a tool to improve digestive diseases. However, the greatest benefit is probably that the information we hope to get from this study may be helpful in guiding healthcare delivery to blacks to reduce their burden of digestive diseases in the future.

What other options are there?

If you chose not to participate in this study, you can call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER to find out more information about cancer studies and clinical trials.

What about confidentiality?

Your records will be confidential. Your name or other information that could identify you will not be used in any reports or publications. Howard University Cancer Center will keep your questionnaire and consent forms. Your information will be stored in a secure locker in a secure office and only authorized staff will have access to it.

What are the costs of the study?

There are no costs to you for participating in this study

Will you be paid?

We are not offering any cash payment. However, you will receive a complimentary water bottle as a token of appreciation for your participation in this study.

Whom do you call if you have questions or problems?

If you have questions about the procedures of this study, please contact Dr. Adeyinka O. Laiyemo at (202) 865-7186 or (202) 865-6100. You are free to ask any questions about the study at any time.

Can you stop being on the study?

Your participation in this study is voluntary. You can choose not to participate at any time.

New Findings

You will be told of any new information about the research study that may affect your health or welfare. You will also be told about any new information that may cause you to change your mind about being in the study.

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Where can you get more information about this study?

If you have questions about the research, or the informed consent process or any other rights as a research subject (participant), please contact the office of the Institutional Review Board (HUIRB) – a group of people who review the research to protect your rights – at (202) 865-8597. You may also call the HUIRB if you wish to discuss this study with someone other than the investigators.

Signature

By signing this consent form, I _____ agree that I have read this informed consent form, the study has been explained to me, my questions have been answered, and I have agreed to take part in this study. I acknowledge that I have received a personal copy of this consent form.

Signature of Participant

Date

Signature of Witness

Date

Signature of Research Staff Member

Date

Initials _____

**CONSENT FOR INVESTIGATIVE PROCEDURES
HOWARD UNIVERSITY CANCER CENTER
WASHINGTON, DC 20060**

GASTROENTEROLOGY CLINIC

Title: Using Patients' Social Contact to Improve Out-Patient Endoscopy among blacks (Colonoscopy)

Principal Investigator: Adeyinka O. Laiyemo, MD, MPH

Tests and/or procedures to be performed

Participating in this study is voluntary. Your refusal to participate will not affect your care by your doctor. However, if you agree to participate, you will be asked to complete an intake form, complete the Lubben Social Network Scale (LSNS-6 version), and give permission for us to obtain and review your colonoscopy reports.

Why is this study being done?

Blacks suffer the highest risk of colon cancer and are more likely to die of colon cancer than other races in the United States. Yet, colon cancer screening with colonoscopy is low among blacks. This study is being done to find out if engaging a patient's social contact that the patient chooses by himself or herself can improve endoscopy services delivery to blacks. This information can be used to design healthcare delivery to blacks, and hopefully, will lead to increase in uptake of colonoscopy for colon cancer screening and reduce deaths from this disease.

Who is doing this study?

The Principal Investigator for this study is Adeyinka O. Laiyemo, MD, MPH at the Howard University Cancer Center. He is a colon cancer prevention expert who was trained at Howard University and the National Institutes of Health (NIH).

Procedures: What is involved in this study?

If you agree to participate in this study the following will happen:

1. You will be asked to sign this consent form that you agree to participate in this study.
2. Then, you will be asked to complete an intake form about yourself and your health.
3. You will also be asked to complete Lubben Social Network Scale (LSNS-6 version)

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4. You will be asked to choose 2 social contacts (persons who you are familiar with such as a family member or friend) who could be engaged by our research team to assist you in completing your colonoscopy with high quality. We will talk to the first contact person you chose, but if the person could not be reached or is not able to participate in the study, we will call the second person you chose.
5. There will be 2 groups of participants in this study. In one group, we will engage the social contact the participant has chosen by explaining to him or her to assist the participant in the process of completing the colonoscopy that the doctor recommended. We will only discuss the process involved in completing a colonoscopy. We will not discuss the medical history of the participant with the social contact under any circumstance. We will not engage the social contact in the second group. You will be randomly assigned to group 1 or group 2.
6. We will call you to remind you of your colonoscopy appointment within one week of your test. If we engaged your social contact, we will also contact him or her to give a reminder about your test.
7. We will check whether you came for your colonoscopy appointment and completed the test. We will request your colonoscopy report from the doctor who performed your colonoscopy.
8. The information from this study will be recorded on paper and later transferred to computer recording.
9. Your information will be confidential and information that can identify you such as your name, address etc will not be analyzed and will not be reported when the result of the study is published. Once the study is completed, all identifying information will be removed completely.
10. We are not offering any cash payment. However, you will receive a complimentary water bottle as a token of appreciation for your participation in this study.

How many people will be involved in the study?

There will be 400 people participating in this study.

How much time would you spend to be part of this study?

We estimate that you will spend 15 minutes in total (10 minutes to complete the intake form and Lubben Social Network Scale and 5 minutes for the reminder phone call before your test).

What are the risks of the study?

The risk of participating in this study is minimal. The things you will be doing have no more risk of harm than you would experience in everyday life. If you find any of the questions we ask you to be upsetting or stressful, you may choose not to answer that question. Also, we can provide you with referrals to resources to help you with those feelings. We can provide referrals to the Howard University Department of Psychiatry if needed. Care will be given at the usual charge to

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you. We will protect your privacy and protect your health information. We will not discuss your medical history with your social contact under any circumstance.

Are there benefits to taking part in the study?

You may receive a direct benefit by taking part in the study through completing the colonoscopy that your doctor recommended for you. Your social contact may also gain more knowledge about colon cancer prevention. However, the greatest benefit is probably that the information we hope to get from this study may be helpful in guiding healthcare delivery to blacks to reduce their burden of colon cancer in the future.

What other options are there?

If you chose not to participate in this study, you can call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER to find out more information about cancer studies and clinical trials.

What about confidentiality?

Your records will be confidential. Your name or other information that could identify you will not be used in any reports or publications. Howard University Cancer Center will keep your questionnaire and consent forms. Your information will be stored in a secure locker in a secure office and only authorized staff will have access to it.

What are the costs of the study?

There are no costs to you for participating in this study

Will you be paid?

We are not offering any cash payment. However, you will receive a complimentary water bottle as a token of appreciation for your participation in this study.

Whom do you call if you have questions or problems?

If you have questions about the procedures of this study, please contact Dr. Adeyinka O. Laiyemo at (202) 865-7186 or (202) 865-6100. You are free to ask any questions about the study at any time.

Can you stop being on the study?

Your participation in this study is voluntary. You can choose not to participate at any time.

New Findings

You will be told of any new information about the research study that may affect your health or welfare. You will also be told about any new information that may cause you to change your mind about being in the study.

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Where can you get more information about this study?

If you have questions about the research, or the informed consent process or any other rights as a research subject (participant), please contact the office of the Institutional Review Board (HUIRB) – a group of people who review the research to protect your rights – at (202) 865-8597. You may also call the HUIRB if you wish to discuss this study with someone other than the investigators.

Signature

By signing this consent form, I _____ agree that I have read this informed consent form, the study has been explained to me, my questions have been answered, and I have agreed to take part in this study. I acknowledge that I have received a personal copy of this consent form.

Signature of Participant

Date

Signature of Witness

Date

Signature of Research Staff Member

Date

Initials_____

**CONSENT FOR INVESTIGATIVE PROCEDURES
HOWARD UNIVERSITY CANCER CENTER
WASHINGTON, DC 20060**

PRIMARY CARE CLINIC

Title: Using Patients' Social Contact to Improve Out-Patient Endoscopy among blacks (Colonoscopy)

Principal Investigator: Adeyinka O. Laiyemo, MD, MPH

Tests and/or procedures to be performed

Participating in this study is voluntary. Your refusal to participate will not affect your care by your doctor. However, if you agree to participate, you will be asked to complete an intake form, complete the Lubben Social Network Scale (LSNS-6 version), and give permission for us to obtain and review your endoscopy reports.

Why is this study being done?

Blacks suffer the highest risk of colon cancer and are more likely to die of colon cancer than other races in the United States. Yet, colon cancer screening with colonoscopy is low among blacks. This study is being done to find out if engaging a patient's social contact that the patient chooses by himself or herself can improve endoscopy services delivery to blacks. This information can be used to design healthcare delivery to blacks, and hopefully, will lead to increase in uptake of colonoscopy for colon cancer screening and reduce deaths from this disease.

Who is doing this study?

The Principal Investigator for this study is Adeyinka O. Laiyemo, MD, MPH at the Howard University Cancer Center. He is a colon cancer prevention expert who was trained at Howard University and the National Institutes of Health (NIH).

Procedures: What is involved in this study?

If you agree to participate in this study the following will happen:

1. You will be asked to sign this consent form that you agree to participate in this study.
2. Then, you will be asked to complete an intake form about yourself, and your health.
3. You will also be asked to complete Lubben Social Network Scale (LSNS-6 version)
4. You will be asked to choose 2 social contacts (persons who you are familiar with such as a family member or friend) who could be engaged by our research team to assist you to make an appointment with a gastroenterologist doctor within the next 3 months and assist you in

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completing your colonoscopy within the next 6 months. We will talk to the first contact person you choose, but if the person could not be reached or is not able to participate in the study, we will call the second person you chose.

5. There will be 2 groups of participants in this study. In one group, we will engage the social contact the participant has chosen by explaining to him or her to assist the participant in the process of completing the colonoscopy that the doctor recommended. We will only discuss the process involved in completing colonoscopy. We will not discuss the medical history of the participant with the social contact under any circumstance. We will not engage the social contact in the second group. You will be randomly assigned to group 1 or group 2.
6. We will contact you in 3 months to check if you have made an appointment with a gastroenterologist
7. We will also contact you in 6 months to check whether you have completed the colonoscopy that your doctor recommended for you. We will request your colonoscopy report from the doctor who performed your colonoscopy.
8. The information from this study will be recorded on paper and later transferred to computer recording.
9. Your information will be confidential and information that can identify you such as your name, address etc will not be analyzed and will not be reported when the result of the study is published. Once the study is completed, all identifying information will be removed completely.
10. We are not offering any cash payment. However, you will receive a complimentary water bottle as a token of appreciation for your participation in this study.

How many people will be involved in the study?

There will be 400 people participating in this study.

How much time would you spend to be part of this study?

We estimate that you will spend 20 minutes in total (10 minutes to complete the intake form and Lubben Social Network Scale, 5 minutes for the phone call at 3 months and 5 minutes for the 6 months phone call.

What are the risks of the study?

The risk of participating in this study is minimal. The things you will be doing have no more risk of harm than you would experience in everyday life. If you find any of the questions we ask you to be upsetting or stressful, you may choose not to answer that question. Also, we can provide you with referrals to resources to help you with those feelings. We can provide referrals to the Howard University Department of Psychiatry if needed. Care will be given at the usual charge to you.

We will protect your privacy and protect your health information. We will not discuss your medical history with your social contact under any circumstance.

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Are there benefits to taking part in the study?

You may receive a direct benefit by taking part in the study by completing the colonoscopy that your doctor recommended for you. Your social contact may also gain more knowledge about colon cancer prevention. However, the greatest benefit is probably that the information we hope to get from this study may be helpful in guiding healthcare delivery to blacks to reduce their burden of colon cancer in the future.

What other options are there?

If you chose not to participate in this study, you can call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER to find out more information about cancer studies and clinical trials.

What about confidentiality?

Your records will be confidential. Your name or other information that could identify you will not be used in any reports or publications. Howard University Cancer Center will keep your questionnaire and consent forms. Your information will be stored in a secure locker in a secure office and only authorized staff will have access to it.

What are the costs of the study?

There are no costs to you for participating in this study

Will you be paid?

We are not offering any cash payment. However, you will receive a complimentary water bottle as a token of appreciation for your participation in this study

Whom do you call if you have questions or problems?

If you have questions about the procedures of this study, please contact Dr. Adeyinka O. Laiyemo at (202) 865-7186 or (202) 865-6100. You are free to ask any questions about the study at any time.

Can you stop being on the study?

Your participation in this study is voluntary. You can choose not to participate at any time.

New Findings

You will be told of any new information about the research study that may affect your health or welfare. You will also be told about any new information that may cause you to change your mind about being in the study.

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Where can you get more information about this study?

If you have questions about the research, or the informed consent process or any other rights as a research subject (participant), please contact the office of the Institutional Review Board (HUIRB) – a group of people who review the research to protect your rights – at (202) 865-8597. You may also call the HUIRB if you wish to discuss this study with someone other than the investigators.

Signature

By signing this consent form, I _____ agree that I have read this informed consent form, the study has been explained to me, my questions have been answered, and I have agreed to take part in this study. I acknowledge that I have received a personal copy of this consent form.

Signature of Participant

Date

Signature of Witness

Date

Signature of Research Staff Member

Date

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Using social contacts to improve endoscopy delivery among blacks: Intake form

Dear Participant:

Studies have shown that blacks suffer a higher occurrence of and death from digestive diseases including colon cancer when compared to other race-ethnicities in the United States. Colon cancer screening can reduce death from this deadly but largely preventable disease. Unfortunately, a high percentage of black patients are not up-to-date with colon cancer screening. The overall goal of this study is to evaluate whether involvement of a social contact (such as spouse, children, neighbors or friends) can improve uptake of out-patient endoscopy including colon cancer screening with colonoscopy among blacks. Your participation is voluntary. All information will be treated as confidential. **Dr Adeyinka O. Laiyemo** is in charge of this study (202-865-6100). Thank you.

General Information – Please write in or circle the appropriate information

Today's date: _____

Last name: _____ First name _____ MI: _____

Cell phone number: () - : Alternate phone: () -

Mailing address: Street: _____ Apt # _____

City: _____ State: _____ Zip code: _____

Date of Birth: / / : Age: _____ years

Sex: 1. Female 2. Male

Ethnicity/Race: Are you a non-Hispanic black? **Yes** **No**

Where were you born? 1. United States 2. Africa 3. Caribbean Islands

How old were you when you moved to the United States? _____ years old

Marital Status: 1. Married/Living as married 2. Single 3. Divorced/Separated 4. Widowed

Highest Education Level: 1. Less than High School
2. High School
3. Some College / Vocational Schools
4. College graduate

Yearly household income: 1. Less than \$25,000
2. \$25,000 - \$34,999
3. \$35,000 - \$49,999
4. \$50,000 - \$74,999
5. Greater than \$75,000

General health and lifestyle questions

Have you ever been diagnosed with colon cancer in the past? **Yes** **No**

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Do you suffer from diabetes?	Yes	No
Do you suffer from high blood pressure (hypertension)?	Yes	No
Have you ever had a heart attack?	Yes	No
Do you suffer from congestive heart failure?	Yes	No
Do you suffer from kidney diseases?	Yes	No
Have you ever had surgery in which part of your colon was removed?	Yes	No
Do you suffer from Crohn's disease (an inflammation of the intestine)?	Yes	No
Do you suffer from ulcerative colitis (an inflammation of the intestine)?	Yes	No
How much do you weigh in pounds? _____ lbs.		
How tall are you? _____ feet _____ inches		
Have you smoked over 100 cigarettes in your lifetime?	Yes	No
Was your last cigarette over 1 year ago?	Yes	No
For how many years did you / have you smoked? _____ years		
How many packets of cigarettes did you / do you smoke per day? _____ packs		
Do you drink alcohol?	Yes	No
What kind of alcohol do you drink? 1.Beer 2.Wine 3.Liquor		
How often do you drink alcoholic beverage? _____ times per week		
Do you take aspirin on a regular basis?	Yes	No
How many times do you take aspirin in a week? _____ times / week		
Do you take NSAIDs (e.g. motrin, aleve, ibuprofen, nuprin) on a regular basis?	Yes	No
How many times do you take NSAIDs in a week? _____ times / week		
Do you engage in leisure exercise on a regular basis?	Yes	No
How often do you engage in (at least 30 minutes) of leisure exercise per week? _____ / week		

Family medical history

Do you know the medical history of your family members?	Yes	No
Do you discuss your medical problems with your family members?	Yes	No
Has anyone in your family ever been diagnosed with colon cancer?	Yes	No

Who was diagnosed with colon cancer and at what age was it diagnosed?

1. Father: Age at diagnosis _____ years
2. Mother: Age at diagnosis _____ years
3. Brother: Age at diagnosis _____ years
4. Sister: Age at diagnosis _____ years
5. Grandfather: Age at diagnosis _____ years
6. Grandmother: Age at diagnosis _____ years

Thank you for your participation

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Previous colon cancer screening experience

Have you been screened for colon cancer previously? **Yes** **No**

If so, which test did you have?

- | | | |
|--|------------|-----------|
| 1. Fecal occult blood test (stool test for blood) | Yes | No |
| 2. Flexible sigmoidoscopy (uses small video camera after enema) | Yes | No |
| 3. Colonoscopy (uses long video camera after full laxative by mouth) | Yes | No |

When did you undergo the last colon cancer screening test? _____ years

SOCIAL CONTACT INFORMATION: (Please inform the social contacts that they may get a call from Howard University on your behalf regarding your outpatient endoscopy).

A. Primary social contact information

Last name: _____ First name _____ MI: _____

Cell phone number: () - ; Alternate phone: () -

Mailing address: Street: _____ Apt # _____

City: _____ State: _____ Zip code: _____

Is this person at least 18 years old (only adults can be facilitators)? **Yes** **No**

What is the sex of this person? 1. Female 2. Male

How is this person related to you? 1. Spouse 2. Sibling (brother/sister) 3. Parent 4. Friend

5. Neighbor 6. Other: Please specify _____

What is the race of this person? 1. Black 2. White 3. Hispanic 4. Asian 5. Other _____

B. Secondary social contact information

Last name: _____ First name _____ MI: _____

Cell phone number: () - ; Alternate phone: () -

Mailing address: Street: _____ Apt # _____

City: _____ State: _____ Zip code: _____

Is this person at least 18 years old (only adults can be facilitators)? **Yes** **No**

What is the sex of this person? 1. Female 2. Male

How is this person related to you? 1. Spouse 2. Sibling (brother/sister) 3. Parent 4. Friend

5. Neighbor 6. Other: Please specify _____

What is the race of this person? 1. Black 2. White 3. Hispanic 4. Asian 5. Other _____

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LUBBEN SOCIAL NETWORK SCALE – 6 (LSNS-6)

FAMILY: *Considering the people to whom you are related by birth, marriage, adoption, etc...*

1. How many relatives do you see or hear from at least once a month?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more
2. How many relatives do you feel at ease with that you can talk about private matters?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more
3. How many relatives do you feel close to such that you could call on them for help?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

FRIENDSHIPS: *Considering all of your friends including those who live in your neighborhood*

4. How many of your friends do you see or hear from at least once a month?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more
5. How many friends do you feel at ease with that you can talk about private matters?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more
6. How many friends do you feel close to such that you could call on them for help?
0 = none 1 = one 2 = two 3 = three or four 4 = five thru eight 5 = nine or more

LSNS-6 total score is an equally weighted sum of these six items. Scores range from 0 to 30

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Has the patient incentive been given to the participant?

Yes

No

Name and signature of participant

Date

Name and signature of witness

Date

Name and signature of Research Staff Member

Date

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Randomization assignment of participant: Usual care Intervention social contact group

Primary social contact communication (if participant is in intervention social contact group)

Date	Phone number called	Social contact reached (Y or N)	Social contact agreed to participate in study (Y or N)	Social contact reminder given (Y or N)

Secondary social contact communication

Date	Phone number called	Social contact reached (Y or N)	Social contact agreed to participate in study (Y or N)	Social contact reminder given (Y or N)

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Transcript of call to the listed social contact for colonoscopy study

Participant's name _____ **Date and Time** _____

Social contact's name _____ **Social contact's phone no** _____

1. INTRODUCTION:

Hello, I am (YOUR NAME). I am calling from Howard University.

2. REASON WHY YOU ARE CALLING:

Mr/Ms (PATIENT'S NAME) is participating in a study which is geared towards preventing and reducing the burden of digestive diseases including colon cancer among African Americans.

In the United States, African Americans are more likely to develop colon cancer and are more likely to die from this disease which can be prevented to a great extent with screening. The problem is that African Americans do not undergo screening as they should.

Mr/Ms (PATIENT'S NAME) gave us your contact information that you could serve as his/her facilitator to complete the colonoscopy which his/her doctor has recommended for him/her. He/she has been scheduled to undergo an out-patient colonoscopy at Howard University Hospital Ambulatory Care Center in the basement of the Towers building in Suite B500 on:

Day: _____ Date: _____ and he/she is to arrive for his/her test at: _____ am / pm

This means that:

- A) You will be asked to remind him/her, encourage him/her, and assist him/her as needed to follow the instructions for preparation for the scheduled colonoscopy.
- B) You may also need to assist him/her in the routine care involved in undergoing a colonoscopy such as with transportation or as an escort.

I want to confirm that you will be willing to assist him/her in this regard (WAIT FOR RESPONSE).

Did the social contact agree to participate? YES NO

If the social contact refused to participate, thank him/her and end conversation.

However, if the social contact agreed to participate, follow the remaining transcript as outlined:

Thank you for agreeing to participate and assist Mr/Ms (PATIENT'S NAME).

Because only adults can be escorts for patients who undergo colonoscopy, previous experiences do matter, and we would like to mail additional information to you, we would need to confirm some information:

How old are you sir/mam? _____ years

Highest Education Level: 1. Less than High School 2. High School 3. Some College / Vocational Schools
4. College graduate

Have you had colonoscopy before? YES NO

Mailing address: Street: _____ Apt # _____

City: _____ State: _____ Zip code: _____

Transcript of call to the listed social contact for colonoscopy study

There are 2 main goals of this study:

1. To ensure that Mr/Ms (**PATIENT'S NAME**) comes for his /her scheduled colonoscopy appointment and
2. To ensure that Mr/Ms (**PATIENT'S NAME**) follows his/her bowel preparation instructions and completes a high quality colonoscopy.

Scheduled colonoscopy appointment: Please encourage Mr/Ms (**PATIENT'S NAME**) to come for his/her scheduled colonoscopy appointment with the gastroenterologist (stomach and colon doctor). If there is any problem and the participant cannot come for his/her scheduled appointment, please encourage him/her to call (202) 865-7186 no less than 24 hours before the scheduled appointment to reschedule.

Colonoscopy: Colonoscopy involves the use of a flexible video endoscope to examine the colorectum. It is recommended that patients undergoing colonoscopy should only drink clear liquid diet (such as apple juice, jello, broth and water) the day before their procedure to minimize further stool formation. They are required to drink bowel laxative (such as polyethylene glycol) in 2 split doses with the first dose ingested the day before the procedure and the second dose ingested in the morning of the procedure no later than 2 hours before the start of the scheduled colonoscopy. The procedure is typically performed under conscious sedation with intravenous administration of a narcotic and a fast acting sedative. The use of sedation mandates the need for an adult escort and patients are asked not to operate automobiles, heavy machinery or make important far-reaching decisions after the procedure because of the potential side effect of sedation which includes forgetfulness. Thus, patients take the day of procedure off from work.

Therefore, Mr/Ms (**PATIENT'S NAME**) will need an escort. We hope you will be able to facilitate this for him/her and you will also encourage him to comply with drinking only clear liquids the day before his/her test and take the laxatives as prescribed. (**WAIT FOR RESPONSE**). We will remind him/her about his/her colonoscopy within one week of his/her test and give you a courtesy call too. We would like you to note how much time you spent in the course of assisting Mr/Ms (**PATIENT'S NAME**) complete this task.

Colonoscopy is also the recommended test following an abnormal result from other screening tests such as stool tests, and it is the test of choice for individuals who have had colon polyps removed in the past. Colonoscopy has the distinct advantages that pre-cancerous lesions seen during the procedure can be removed during the procedure and it is the endoscopic procedure that can examine all parts of the colon.

Colonoscopy is generally safe but there is a small risk of bleeding after the procedure especially if a large pre-cancerous polyp is removed but doctors use cautery and clips to minimize the risk of bleeding. There is also a very small risk of perforation (going through the wall of the colon), but this is very uncommon because the test is done with a video camera and doctors see the colon when they advance the scope and it is not a blind test.

Overall, the quality colonoscopy test is that in which there is no stool in the colon and the doctor is able to see the wall of the colon very well so that if there is a pre-cancerous polyp, it can be seen and removed to prevent cancer in the future. This is what we want you to encourage Mr/Ms (**PATIENT'S NAME**) to achieve.

Do you have any question Mr/Ms (SOCIAL CONTACT'S NAME**)?**
(If not, or when the questions have been answered):

We will mail an information booklet to you on colonoscopy to serve as reference as you continue to assist Mr/Ms (**PATIENT'S NAME**). If you have any question later, you can call us at (202) 865-7186 and discuss with Dr. Laiyemo, a gastroenterologist (a stomach and colon doctor) who is conducting this study.

Thank you very much.

Research staff name and signature _____ Date and time _____

Participant's name_____ **Date and Time**_____

Social contact's name _____ **Social contact's phone no** _____

Hello, I am (YOUR NAME). I am calling from Howard University.

Mr/Ms (**PATIENT'S NAME**) is participating in a study which is geared towards preventing and reducing the burden of digestive diseases including stomach ulcer among African Americans.

Mr/Ms (**PATIENT'S NAME**) gave us your contact information that you could serve as his/her facilitator to complete the upper endoscopy which his/her doctor has recommended for him/her. He/she has been scheduled to undergo an out-patient upper endoscopy at Howard University Hospital Ambulatory Care Center in the basement of the Towers building in Suite B500 on:

Day: _____ Date: _____ and he/she is to arrive for his/her test at: _____ am / pm

A) You will be asked to remind him/her, encourage him/her, and assist him/her as needed to follow the instructions for preparation for the scheduled upper endoscopy.

B) You may also need to assist him/her in the routine care involved in undergoing an upper endoscopy such as with transportation or as an escort.

I want to confirm that you will be willing to assist him/her in this regard (**WAIT FOR RESPONSE**).

Did the social contact agree to participate?	YES	NO
--	-----	----

If the social contact refused to participate, thank him/her and end conversation.

However, if the social contact agreed to participate, follow the remaining transcript as outlined:

Thank you for agreeing to participate and assist Mr/Ms (PATIENT'S NAME).

Because only adults can be escorts for patients who undergo upper endoscopy, previous experiences do matter, and we would like to mail additional information to you, we would need to confirm some information:

How old are you sir/mam? _____ years

Highest Education Level: 1. Less than High School 2. High School 3. Some College / Vocational Schools
4. College graduate

Have you had upper endoscopy before? **YES** **NO** Have you had colonoscopy before? **YES** **NO**

Mailing address: Street: Apt #

City: _____ State: _____ Zip code: _____

Transcript of call to the listed social contact for upper endoscopy study

There are 2 main goals of this study:

1. To ensure that Mr/Ms (**PATIENT'S NAME**) comes for his /her scheduled upper endoscopy appointment and
2. To ensure that Mr/Ms (**PATIENT'S NAME**) follows his/her instructions and completes a high quality upper endoscopy.

Scheduled upper endoscopy appointment: Please encourage Mr/Ms (**PATIENT'S NAME**) to come for his/her scheduled upper endoscopy appointment with the gastroenterologist (stomach and colon doctor). If there is any problem and the participant cannot come for his/her scheduled appointment, encourage him/her to please call **(202) 865-7186** no less than 24 hours before the scheduled appointment to reschedule.

Upper endoscopy: Upper endoscopy involves the use of a flexible video endoscope to examine the food pipe, stomach, and the initial part of the small bowel to diagnose digestive diseases including stomach ulcer and stomach cancer. It is preferable that a patient undergoing the procedure should eat a light dinner the day before the procedure and it is recommended that patients do not eat or drink after midnight in order to ensure that their stomach will be empty, devoid of food and liquids at the time of the upper endoscopy test.

The procedure is typically performed under conscious sedation with intravenous administration of a narcotic and a fast acting sedative. The use of sedation mandates the need for an adult escort and patients are asked not to operate automobiles, heavy machinery or make important far-reaching decisions after the procedure because of the potential side effect of sedation which includes forgetfulness. Thus, patients take the day of procedure off from work.

Therefore, Mr/Ms (**PATIENT'S NAME**) will need an escort. We hope you will be able to facilitate this for him/her and you will also encourage him to comply with the preparation before the procedure as recommended. (**WAIT FOR RESPONSE**). We will remind him/her about his/her upper endoscopy within one week of his/her test and give you a courtesy call too. We would like you to note how much time you spent in the course of assisting Mr/Ms (**PATIENT'S NAME**) complete this task.

Upper endoscopy is generally very safe but there is a small risk of bleeding after biopsy but doctors use cautery and clips to minimize the risk of bleeding. There is also a very small risk of perforation (going through the wall of the stomach), but this is very uncommon because the test is done with a video camera and doctors see the stomach well when they advance the scope and it is not a blind test.

Overall, the high quality upper endoscopy test is that in which there is no food or liquid in the stomach and the doctor is able to see the walls of the food pipe (esophagus), stomach and initial part of the small bowel (duodenum) very well so that diagnosis can be easily made and effective treatment of digestive diseases can be started. This is what we want you to encourage Mr/Ms (**PATIENT'S NAME**) to achieve.

Do you have any question Mr/Ms (SOCIAL CONTACT'S NAME**)?**
(If not, or when the questions have been answered):

We will mail information to you on upper endoscopy to serve as reference as you continue to assist Mr/Ms (**PATIENT'S NAME**). If you have any question later, you can call us at (202) 865-7186 and discuss with Dr. Laiyemo, a gastroenterologist (a stomach and colon doctor) who is conducting this study.

Thank you very much.

Research staff name and signature _____ Date and time _____

Participant's name_____ **Date and Time**_____

Social contact's name_____ **Social contact's phone no**_____

Hello, I am **(YOUR NAME)**. I am calling from Howard University.

Mr/Ms (**PATIENT'S NAME**) is participating in a study which is geared towards preventing and reducing the burden of digestive diseases including colon cancer among African Americans.

In the United States, African Americans are more likely to develop colon cancer and are more likely to die from this disease which can be prevented to a great extent with screening. The problem is that African Americans do not undergo screening as they should.

Mr/Ms (**PATIENT'S NAME**) gave us your contact information that you could serve as his/her facilitator to complete the colonoscopy which his/her doctor has recommended for him/her. This means that:

- A) You will be asked to remind him/her, encourage him/her, and assist him/her as needed to make an appointment to see a gastroenterologist (a stomach and colon doctor) to schedule his/her colonoscopy test. This should be completed within 3 months
- B) You will be asked to remind him/her, encourage him/her, and assist him/her as needed to follow the instructions for preparation for the colonoscopy after it has been scheduled.
- C) You may also need to assist him/her in the routine care involved in undergoing a colonoscopy such as with transportation or as an escort.

I want to confirm that you will be willing to assist him/her in this regard (**WAIT FOR RESPONSE**).

Did the social contact agree to participate?	YES	NO
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If the social contact refused to participate, thank him/her and end conversation.

However, if the social contact agreed to participate, then follow the remaining transcript as outlined:

Thank you for agreeing to participate and assist Mr/Ms (PATIENT'S NAME).

We would need to confirm some information. Because only adults can be escorts for patients who undergo colonoscopy, previous experiences do matter, and we would like to mail additional information to you:

How old are you sir/mam? _____ years

Highest Education Level: 1. Less than High School 2. High School 3. Some College / Vocational Schools
4. College graduate

Have you had colonoscopy before?	YES	NO
---	------------	-----------

Mailing address: Street: _____ Apt # _____

City: _____ State: _____ Zip code: _____

Transcript of call to the listed social contact for primary care study

There are 2 main goals of this study:

1. To ensure that Mr/Ms (**PATIENT'S NAME**) makes an appointment and sees a gastroenterologist (stomach and colon doctor) within 3 months
2. To ensure that Mr/Ms (**PATIENT'S NAME**) follows instructions and completes a high quality colonoscopy within 6 months.

Scheduling appointment: Please encourage Mr/Ms (**PATIENT'S NAME**) to make an appointment with a gastroenterologist. For Howard University gastroenterologists, the number to call is (202) 865-4700 and Mr/Ms (**PATIENT'S NAME**) can generally be seen within one month. He will be scheduled for his colonoscopy during the visit. If the doctor has referred him to be seen by another gastroenterologist, that is also okay, but we will still expect Mr/Ms (**PATIENT'S NAME**) to complete his/her clinic visit within 3 months.

Colonoscopy: Colonoscopy involves the use of a flexible video endoscope to examine the colorectum. It is recommended that patients undergoing colonoscopy should only drink clear liquid diet (such as apple juice, jello, broth and water) the day before their procedure to minimize further stool formation. They are required to drink bowel laxative (such as polyethylene glycol) in 2 split doses with the first dose ingested the day before the procedure and the second dose ingested in the morning of the procedure no later than 2 hours before the start of the scheduled colonoscopy. The procedure is typically performed under conscious sedation with intravenous administration of a narcotic and a fast acting sedative. The use of sedation mandates the need for an adult escort and patients are asked not to operate automobiles, heavy machinery or make important far-reaching decisions after the procedure because of the potential side effect of sedation which includes forgetfulness. Thus, patients take the day of procedure off from work.

Therefore, Mr/Ms (**PATIENT'S NAME**) will need an escort. We hope you will be able to facilitate this for him/her and you will also encourage him to comply with drinking only clear liquids the day before his/her test and take the laxatives as prescribed. (**WAIT FOR RESPONSE**). We would like you to note how much time you spent in the course of assisting Mr/Ms (**PATIENT'S NAME**) complete this task.

Colonoscopy is also the recommended test following an abnormal result from other screening tests such as stool tests, and it is the test of choice for individuals who have had colon polyps removed in the past. Colonoscopy has the distinct advantages that pre-cancerous lesions seen during the procedure can be removed during the procedure and it is the endoscopic procedure that can examine all parts of the colon.

Colonoscopy is generally safe but there is a small risk of bleeding after the procedure especially if a large pre-cancerous polyp is removed but doctors use cautery and clips to minimize the risk of bleeding. There is also a very small risk of perforation (going through the wall of the colon), but this is very uncommon because the test is done with a video camera and doctors see the colon when they advance the scope and it is not a blind test.

Overall, the quality colonoscopy test is that in which there is no stool in the colon and the doctor is able to see the colon very well so that if there is a pre-cancerous polyp, it can be seen and removed to prevent cancer in the future. This is what we want you to encourage Mr/Ms (**PATIENT'S NAME**) to achieve.

Do you have any question Mr/Ms (SOCIAL CONTACT'S NAME**)?**
(If not, or when the questions have been answered):

We will mail information to you on colonoscopy to serve as reference as you continue to assist Mr/Ms (**PATIENT'S NAME**). If you have any question later, you can call us at (202) 865-7186 and discuss with Dr. Laiyemo, a gastroenterologist (a stomach and colon doctor) who is conducting this study.

Thank you very much.

Research staff name and signature _____ Date and time _____



Gastroenterology Division

Howard University Hospital

Colonoscopy Patient Instruction Sheet Split Dose Bowel Preparation (prescription required)

Patient Name: _____

Physician: _____

Procedure Date: _____

Arrival Time: _____

Instructions for bowel preparation for Colonoscopy:

You will receive a prescription for a laxative called "Golytely", which is 1 gallon or 4 liters of laxative.

1. On the day before your procedure. Do Not Eat any solid food. Only drink clear liquids for the entire day. Clear liquids include jello, apple juice, white grape juice, water, bouillon, etc. We ask that you drink plenty of water during the day so that you are well hydrated prior to starting the laxative.
2. At _____ pm on the day before your procedure begin to drink half of the Golytely (2 liters) laxative. Drink one 8 ounce glass every 10 – 15 minutes. Please complete drinking half or 2 liters of laxative within 1 ½ - 2 hours.
3. At _____ in the evening/in the morning drink the remaining Golytely laxative (2 liters). Drink one 8 Ounce glass every 10 -15 minutes. Please complete drinking the entire 2 liters of laxative within 1 ½ - 2 hours.
4. Please do not eat any food during the evening or the night before your procedure. but you may continue to drink clear liquids (water) until you do to bed.
5. The morning of your procedure (do not eat anything) arrive at Howard University Hospital at the time stated above and go directly to the Outpatient surgery Center located in the basement of the Towers building (on the 5th street side of HUH).
6. Please make arrangements for someone to escort you home after your procedure. You will be given medications to put you in a light sleep during the procedure and will not be able to drive home afterwards. You must have someone to escort you home after the test, even if you are using public transportation.

IMPORTANT: Do not take any blood thinners within one week of your procedure.

If you have any questions please call Gastroenterology Division at 202-865-3290 or after normal business hours call 202-865-6100 and page the Gastroenterology Fellow on-call.

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IRB# 11/06/2012

MAR 28 2014

Expiration Date

MAR 27 2015

**Gastroenterology Division
Howard University Hospital
EGD/ Upper Endoscopy Patient Instruction Sheet**

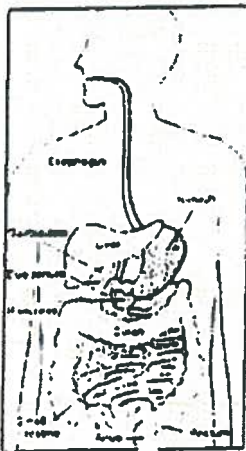
Patient Name: _____

Physician: _____

Procedure Date: _____

Arrival Time: _____

Instructions for Upper Endoscopy (EGD):



- You are scheduled to have an esophagogastroduodenoscopy (EGD) or endoscopic ultrasound (EUS).
- During this procedure the doctor needs your stomach to be completely empty. For this reason you are asked to fast (consume no food or drink) for no less than 8 hours prior to the procedure. As a precaution you should not have anything by mouth after midnight the night before your exam.

- You may take blood pressure medications the morning of your exam. **IF YOU HAVE DIABETES** do not take your pills the morning of the exam.
- The morning of your exam arrive at Howard University Hospital and go to the Outpatient Surgery Center (located in the basement of the Towers Building) and sign in.
- Please make arrangements for someone to escort you to and from your procedure. You will be given medications to put you in a light sleep during the procedure and will not be able to drive home afterwards. You must have someone to escort you home after the test, even if you are using public transportation. If you do not have an escort we will not be able to perform your procedure.
- If you have any questions please call the Gastroenterology Division at Howard University Hospital at 202-365-6100 and page the Gastroenterology Fellow on-call

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Colorectal cancer is cancer that forms in either the colon or the rectum.

CANCER IS SECOND ONLY TO

heart disease as the leading cause of death in the United States and **COLORECTAL CANCER** is the second leading cause of cancer death in the states.

African-Americans have the highest risk of developing and dying from colorectal cancer than any other racial group in the country. The reasons for this are not yet understood. **Learn what you can do today to REDUCE YOUR CHANCE of getting colorectal cancer in the future!**

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Howard University Cancer Center



COLORECTAL CANCER

WHAT YOU NEED TO KNOW:
Early Screening and Detection
is Your Best Protection

HUCC
Howard University
Cancer Center

2041 Georgia Avenue, NW
Washington, DC 20060-0001

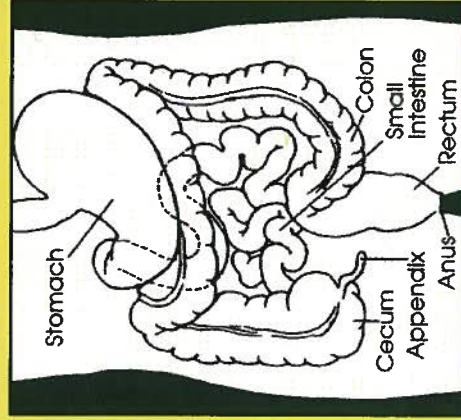
Phone: 202.806.7697
Fax: 202.667.1686

RISK FACTORS

Associated with Colorectal Cancer

ANYONE CAN DEVELOP COLORECTAL CANCER.
However, your risk may be higher if you have any of the following:

- Higher dietary intake of fat, particularly animal fat
- Low fiber intake
- Low intake of fruit and vegetables
- History of inflammatory bowel disease
- History of ulcerative colitis or Crohn's colitis
- Personal or family history of colorectal cancer or polyps
- Obesity
- History of smoking



WHAT YOU CAN DO to Reduce the Chance of Getting Colorectal Cancer

- Increase dietary intake of fiber (through fruits, vegetables, legumes, and whole grain breads and cereals)
- Avoid fatty foods and limit your consumption of meat, especially red meat
- Eat 5 servings of fruits and vegetables daily
- Eat folate rich foods such as leafy green vegetables
- Maintain a healthy body weight
- Try to get at least 30 minutes of moderate activity five or more times per week
- Limit consumption of alcoholic beverages
- If you have a family history of colorectal cancer in a first degree relative (mother, father, sister, or child), see your doctor at an early age, so that appropriate screening guidelines can be set for you. If your affected family member was diagnosed with cancer at a young age, your physician will want to have you tested for colorectal cancer earlier than most people.

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American Cancer Society

RECOMMENDATIONS

(Asymptomatic persons with no known risk factors)

Beginning at age 50, men and women should follow one of the examination schedules listed below:

- A fecal occult blood test¹ every year.
- A flexible sigmoidoscopy² every five years.*
- A colonoscopy² every 10 years.*
- A double-contrast barium enema³ every 5 years.*

* A digital rectal exam should be done at the same time as sigmoidoscopy, colonoscopy, or double-contrast barium enema. People who are at moderate or high risk for colorectal cancer should talk with a doctor about a different testing schedule.

1. This test checks for hidden (occult) blood in the stool.

2. These are tests in which a doctor looks through a lighted tube to check for polyps, tumors, or other abnormalities.

3. This test involves taking a series of x-rays of the colon and rectum.

Colorectal cancer can cause many symptoms.

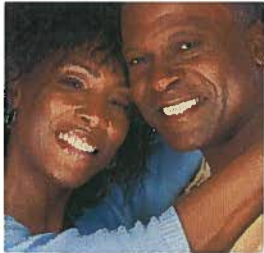
Warning signs to watch for include:

- sudden diarrhea or constipation;
- blood in the stool;
- pencil-like or narrow stools;
- change in bowel habits;
- general abdominal discomfort (frequent gas pains, bloating, fullness, and/or cramps);
- frequent gas pains;
- feeling of incomplete bowel emptying;
- unexplained weight loss;
- constant tiredness; and,
- loss of appetite.

If you are experiencing any of these symptoms, just remember this—don't diagnose yourself and don't delay. See your doctor or phone Howard University Cancer Center for an appointment.

Health Bulletin

HOWARD UNIVERSITY CANCER CENTER



Get Checked!

50 or Older?

Get a Colonoscopy to Prevent Colon Cancer

A colonoscopy tests for—and can also prevent—colon cancer. Did you know?

- Colonoscopy detects more than 95% of early colon cancer.
- Colonoscopy is the only test that can prevent colon cancer by identifying pre-cancerous polyps—or small growths and removing them during the procedure.

Risk Factors for Colon Cancer

- Being 50 or older. More than 90% of colon cancers occur in this age group.
- Personal or family history:
 - A history of colon polyps, colon cancer or other cancers in your immediate family—parents, brothers, sisters—increases your risk.
- Smoking
- Being overweight or obese.
- Ethnicity: African-Americans
- Having other colon diseases such as ulcerative colitis or Crohn's disease.

How to lower your risk

- **Quit smoking.** For free help quitting in the District of Columbia, call 1 (800) QUIT-NOW (784-8669).
- **Exercise regularly.** Get at least 30 minutes of moderate physical activity at least 5 days a week.
- Eat a healthy diet high in fiber and low in red meat.



Colon cancer is one of the most preventable—but least prevented—of all cancers.



Colonoscopy is usually needed only once every 10 years if test results are normal. Other screening tests are needed more often.

Other Tests for Colon Cancer

Any test is better than no test. A positive result on any of these tests must be followed by colonoscopy.

Fecal Occult Blood Test (FOBT) and Fecal Immunochemical Test (FIT)

- Both FOBT and FIT check for hidden blood in the stool. Each includes instructions on how to take stool samples at home and return them for testing.
- They should be done every year.

Sigmoidoscopy

- Similar to colonoscopy but examines less than half of the colon.
- Should be done every 5 years.

Barium Enema X-Ray

- A liquid is injected into your bowels followed by a series of X-Rays.
- Should be done every 5 years.

Virtual Colonoscopy

- Uses X-rays and computers to produce images of the colon.
- Should be done every 5 years, although this procedure is still fairly new and continues to be studied.

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Expiration Date

MAR 27 2015

Colonoscopy Countdown



What to Expect and How to Prepare

What to Expect

- Colonoscopy examines the entire colon using a flexible tube with a camera at one end.
- The exam usually lasts about 30 minutes.
- Colonoscopy is safe and usually painless. There may be some discomfort, but patients are usually given a sedative to help them relax.
- Risk of complications is very small.

How to Prepare

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Expiration Date

MAR 27 2015

7 days before	<ul style="list-style-type: none"> ■ Your doctor will probably ask you to stop taking aspirin, aspirin substitutes and iron medications. ■ Your doctor may also instruct you to stop taking some prescription medicines.
6 - 2 days before	<ul style="list-style-type: none"> ■ You can eat a regular diet.
1 day before	<ul style="list-style-type: none"> ■ Consume only clear liquids (water, apple juice, coffee or tea without milk or cream, clear broth) the day before and until you go to bed. ■ Your doctor will ask you to take medicine to empty your colon.
Day of the test	<ul style="list-style-type: none"> ■ Do not eat or drink anything the day of your test except your bowel preparation laxatives and regular medications.
A few hours after the test	<ul style="list-style-type: none"> ■ Most people feel better after the sedative has worn off. ■ You will need to be accompanied home by an adult. The DC Screen for Life Program may be able to help arrange transportation as needed. ■ Most people can begin eating regular meals right away.
1 day later	<ul style="list-style-type: none"> ■ You should feel better and be able to resume all normal activities within a day.

Howard University Hospital
2041 Georgia Avenue, NW
Washington, DC 20060

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION

Patient's Name: _____

Patient's Address: _____

Patient's Date of Birth: _____ OR Social Security # _____

I hereby authorize disclosure of protected health information about me as follows:

_____ is authorized to disclose medical information (Facility or Doctor)
about me.

The information may be disclosed to:

Name: ADEYINKA O. LAIYEMO, MD, MPH
Address: HOWARD UNIVERSITY, 2041 GEORGIA AVE, NW
WASHINGTON, DC 20060
Phone: (202) 865-7186 Fax: (202) 865-4607

The specific information to be disclosed is:

REPORTS OF ENDOSCOPY, UPPER ENDOSCOPY, EGD, COLONOSCOPY
LOWER GI ENDOSCOPY, PROCEDURE NOTES AND PATHOLOGY REPORTS

From: _____ (Date) To: _____ (Date)

The purpose of the requested disclosure is:

I AM A RESEARCH STUDY PARTICIPANT
AT HOWARD UNIVERSITY

I acknowledge that the information disclosed pursuant to this authorization may be subject to re-disclosure by the recipient and no longer protected by Federal Law.

I understand that my health record may include information pertaining to the treatment of drug and alcohol abuse, mental illness, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency (HIV); sexually transmitted disease, tuberculosis or genetics. IF YOU DO NOT WISH THIS INFORMATION TO BE RELEASED, PLEASE INITIAL. DO NOT
RELEASE _____

I have the right to revoke this authorization by written notice to _____. I understand that actions taken in reliance on this authorization cannot be reversed, and my revocation will not affect those actions.

This authorization expires on _____ (Date) or upon the following event: _____

If no date is specified, this authorization will expire in six months from the date of signature below.

(Signature of Patient or Personal Representative)

(Date of Signature)

If signed by a personal representative, a description of the representative's authority to act is as follows: _____

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Expiration Date

MAR 28 2014

MAR 27 2015

HELP US PREVENT COLON CANCER!!!

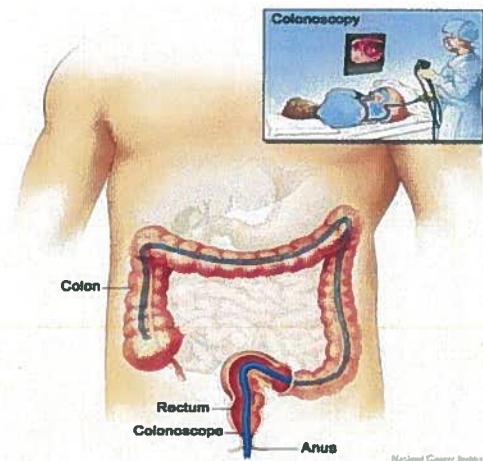
LET US IMPROVE COLONOSCOPY SCREENING!!!

Fact #1: Blacks are more likely to be diagnosed with colon cancer and are more likely to die of colon cancer when compared to other races in the United States

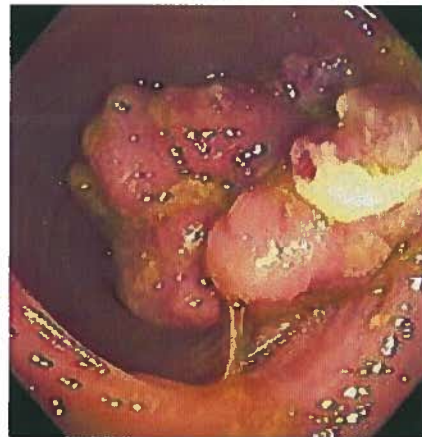
Fact #2: Colon cancer can be reduced with colonoscopy test

Fact #3: Unfortunately, only about 50% of age eligible blacks have been screened

Colonoscopy



Colon Cancer



We are conducting a study to evaluate whether involvement of a patient's social contact (such as family members and friends) will improve uptake of colonoscopy screening. Participants in this study will receive a free bowel laxative preparation for their scheduled colonoscopy.

If you have been scheduled for colonoscopy or if you are going to be scheduled for colonoscopy and you would like to participate in our study, kindly inform our staff.

You can call (202) 865-7186 for more information about ["The Colonoscopy Compliance Study"](#)

Thank you very much

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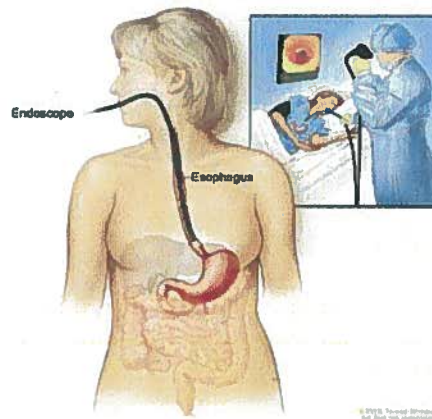
LET US IMPROVE UPPER ENDOSCOPY COMPLIANCE!!!

Fact #1: Blacks suffer a higher burden from gastrointestinal diseases that are commonly prevented, diagnosed or treated with endoscopy such as peptic ulcer disease due to higher prevalence of *Helicobacter Pylori* infection

Fact #2: A high percentage of patients miss their endoscopy appointments

Fact #3: There is a need to improve endoscopy attendance

Upper Endoscopy



We are conducting a study to evaluate whether involvement of a patient's social contact (such as family members and friends) will improve attendance to endoscopy. Participants in this study will receive a complimentary water bottle as a token of appreciation for participating in the study.

If your doctor has recommended an upper endoscopy test for you and you would like to participate in our study, kindly inform our staff.

For more information, please call (202) 865-7186 about ["The Upper Endoscopy Study"](#).

Thank you very much

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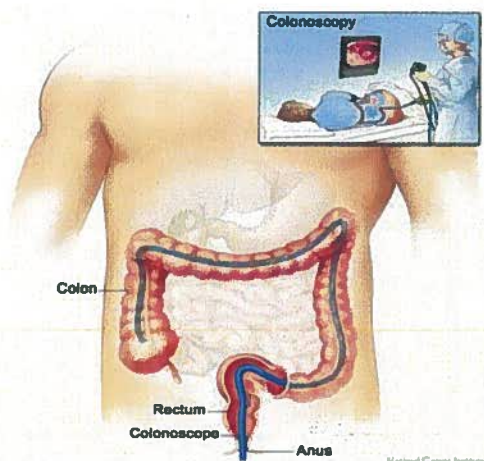
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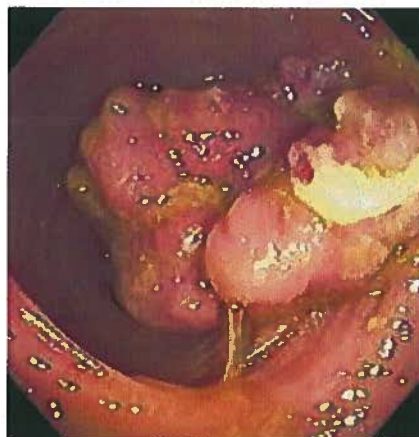
Fact #2: Colon cancer can be reduced with colonoscopy test

Fact #3: Unfortunately, only about 50% of age eligible blacks have been screened

Colonoscopy



Colon Cancer



We are conducting a study to evaluate whether involvement of a patient's social contact (such as family members and friends) will improve uptake of colonoscopy screening. Participants in this study will receive a \$10 gift card as a token of appreciation for participating in the study.

If your doctor has recommended colonoscopy test for colon cancer screening and you would like to participate in our study, kindly inform our staff.

For more information, please call (202) 865-7186 about ["The Colonoscopy Primary Care Study"](#).

Thank you very much

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Social contact intervention: results of colonoscopy study

1

G_ID number: _____

General Information – Please **write in** or **circle** the appropriate information

Last name: _____ First name _____ MI: _____

Age: _____ years

Sex: 1. Female 2. Male

Randomization assignment: Usual Care Intervention Social Contact

Social contact results

A. Did the primary social contact agree to participate?	Yes	No
B. Was the secondary social contact engaged?	Yes	No
C. Was a social contact involved?	Yes	No

AIM 1 results: Attendance to the scheduled colonoscopy appointment

D. Did the participant reschedule the colonoscopy?	Yes	No
E. Did the participant show up for the colonoscopy?	Yes	No

AIM 2 results: Quality and findings of colonoscopy performed

F. Was the colonoscopy performed?	Yes	No
G. When was the colonoscopy performed?	_____	
H. Was the cecum reached during colonoscopy?	Yes	No

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Objective results from colonoscopy

A. Adequacy of bowel preparation by endoscopist

1. Poor / inadequate
2. Fair
3. Good
4. Excellent

B. Diverticulosis

Yes No

C. Diverticulosis location

1. Rectum
2. Distal (sigmoid, descending, splenic flexure)
3. Proximal (transverse, ascending, cecum)
4. Both distal and proximal

D. Hemorrhoids

Yes No

E. Polyps

Yes No

F. Is the polyp hyperplastic?

Yes No If Yes how many _____

G. Hyperplastic polyp location

1. Rectum
2. Distal (sigmoid, descending, splenic flexure)
3. Proximal (transverse, ascending, cecum)
4. Both distal and proximal

H. Is the polyp adenomatous?

Yes No If Yes how many _____

I. Adenomatous polyp location

1. Rectum
2. Distal (sigmoid, descending, splenic flexure)
3. Proximal (transverse, ascending, cecum)
4. Both distal and proximal

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Social contact intervention: results of upper endoscopy (EGD) study

1

G_ID number: _____

General Information – Please write in or circle the appropriate information

Last name: _____ First name _____ MI: _____

Age: _____ years

Sex: 1. Female 2. Male

Randomization assignment: Usual Care Intervention Social Contact

Social contact results

A. Did the primary social contact agree to participate?	Yes	No
B. Was the secondary social contact engaged?	Yes	No
C. Was a social contact involved?	Yes	No

AIM 1 results: Attendance to the scheduled upper endoscopy appointment

D. Did the participant reschedule the upper endoscopy?	Yes	No
E. Did the participant show up for the upper endoscopy?	Yes	No

AIM 2 results: Quality and findings of upper endoscopy performed

F. Was the upper endoscopy performed?	Yes	No
G. When was the upper endoscopy performed?	_____	
H. Was the duodenum reached during upper endoscopy?	Yes	No
I. Was there any food debris in the stomach at upper endoscopy?	Yes	No

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Objective results from upper endoscopy

EGD findings

1. Indication:

a) Abdominal pain:	Yes	No
b) Gastrointestinal bleeding:	Yes	No
c) Reflux/pyrosis/dyspepsia/heartburn:	Yes	No
d) History of gastric ulcer:	Yes	No
e) Weight loss:	Yes	No
f) Screening for bariatric surgery:	Yes	No
g) Anemia:	Yes	No
h) Diarrhea:	Yes	No
i) Fecal occult blood positive (FOBT) :	Yes	No
j) Other. Please specify _____		

2. EGD results by location

a) Esophagus:

i. Gastroesophageal junction is at _____		cm
ii. Esophagitis:	Yes	No
iii. Varices:	Yes	No
iv. Hiatal hernia:	Yes	No
v. Other. Please specify _____		

b) Stomach:

i. Gastritis:	Yes	No
ii. Gastric ulcer:	Yes	No
iii. Gastric polyps:	Yes	No
iv. Other. Please specify _____		

c) Duodenum:

i. Duodenitis:	Yes	No
ii. Duodenal ulcer:	Yes	No
iii. Other. Please specify _____		

3. <u>H. Pylori positive:</u>	Yes	No
4. <u>Gastric cancer:</u>	Yes	No
5. <u>Intestinal metaplasia:</u>	Yes	No

Social contact intervention: results of primary care study

1

G_ID number: _____

General Information – Please **write in** or **circle** the appropriate information

Last name: _____ First name _____ MI: _____

Age: _____ years

Sex: 1. Female 2. Male

Randomization assignment: Usual Care Intervention Social Contact

Social contact results

A. Did the primary social contact agree to participate?	Yes	No
B. Was the secondary social contact engaged?	Yes	No
C. Was a social contact involved?	Yes	No

AIM 1 results: Scheduling an appointment with a gastroenterologist within 3 months

D. Did the participant schedule an appointment with a gastroenterologist?	Yes	No
E. Has the participant consulted a gastroenterologist?	Yes	No
F. When did the participant see a gastroenterologist?	_____	

AIM 2 results: Completing the colonoscopy within 6 months

G. Did the participant complete his/her colonoscopy?	Yes	No
H. When did the participant complete the colonoscopy?	_____	
I. Was the colonoscopy completed within 3 months of study enrolment?	Yes	No
J. Was the cecum reached during colonoscopy?	Yes	No

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Objective results from colonoscopy

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