

Question: Does your manuscript contain the institutional review board statement in the main text?

Answer: Yes. The study was approved by the Institutional Review Board of Howard University. Please see attached IRB approval (IRB-12-MED-17) below.

HOWARD UNIVERSITY

Office of Regulatory Research Compliance

Date: May 10, 2012

To: Adeyinka O. Laiyemo, M.D., MPH, FACP
Department of Medicine

From: Marline Brown-Walthall, MPH, Sr. Compliance Administrator
Institutional Review Board

Jamie Rotimi, M.S., Compliance Officer
Institutional Review Board

Title: **IRB-12-MED-17:** Predicting Tolerability of Bowel Preparation Laxative for Colonoscopy Using Beverage Taste Preferences

Action: Expedited Review- *New Faculty Research*

Approval Date: May 7, 2012

Expiration Date: May 6, 2013

The above-referenced submission was approved by expedited review on May 7, 2012. Approval for this study is through **May 6, 2013**. The IRB requires that you submit an application for annual renewal at the end of the approval period and/or at the study's completion.

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 **90 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

Yonette F. Thomas, Ph.D., AVP Research Compliance

MAY 07 2012

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

Expiration Date

MAY 06 2013

Title: Predicting tolerability of bowel preparation laxative for colonoscopy using beverage taste preferences (Taste test model development phase 1).

Principal Investigator: Adeyinka O. Laiyemo, MD, MPH

Tests and/or procedures to be performed

Study participants will be asked to complete a questionnaire and drink 10 cc (equivalent to 2 teaspoons) of each of 3 laxatives in randomly selected order (ABC, BCA, CAB).

(A) Unflavored Polyethylene glycol electrolyte solution (unflavored golytely)

(B) Flavored Polyethylene glycol electrolyte solution (flavored golytely)

(C) Moviprep ®

This activity is voluntary but the minimum requirement for participation is to complete the questionnaire.

Why is this study being done?

This study is being done to find out if we can use the beverage intake taste preferences of volunteers to predict the bowel laxative preparations that they will tolerate. This information can be used to improve the experience of people under going colonoscopy, and hopefully, will lead to increase in uptake of colonoscopy for colon cancer screening and reduce deaths from this disease.

Participating in this study is voluntary. Your refusal to participate will not affect your care by your doctor.

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 a consent form that you agree to participate
2. Then, you will be asked to complete a questionnaire about yourself, your health and your beverage intake pattern.
3. You will be asked to drink 10cc (2 teaspoonful) of three different FDA approved bowel laxatives and you will be asked to rank them based on your preference

Initials_____

4. Your responses will be used to develop a predictive model for bowel laxative preference based on your beverage preferences, intake patterns, and your socio-demographic characteristics.
5. The information will be recorded on paper and later transferred to computer recording.
6. 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.
7. You will receive a gift item or \$10 gift card as a token of appreciation for your involvement in this study.

How many people will be involved in the study?

There will be 800 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 questionnaire and 5 minutes to taste the 3 bowel preparation laxatives).

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. The total amount of bowel laxatives you will taste is small and is not expected to induce bowel movement or cause you to develop diarrhea. Furthermore, the 3 bowel laxatives being tasted contain the same active ingredient (polyethylene glycol) with slightly different formulations and flavoring. Therefore, we do not anticipate any additional discomfort or pain from tasting the 3 preparations as compared to tasting just one bowel preparation laxative.

Are there benefits to taking part in the study?

You will not receive a direct benefit by taking part in the study. However, the information we hope to get from this study may be helpful in making bowel preparation for colonoscopy easier for people in the future and help in preventing colorectal cancer. A benefit that you may derive personally is that you will know your own bowel preparation laxative choice should you need colonoscopy in the future.

What other options are there?

If you choose 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.

APPROVED
Howard University
IRB

MAY 07 2012

Expiration Date

MAY 06 2013

Initials _____

MAY 07 2012

MAY 06 2013

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?

You will receive a gift item or \$10 gift card 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.

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 Research Staff Member

Date

Initials _____

MAY 07 2012

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

MAY 06 2013

Title: Predicting tolerability of bowel preparation laxative for colonoscopy using beverage taste preferences (**Taste test model validation phase 2**).

Principal Investigator: Adeyinka O. Laiyemo, MD, MPH

Tests and/or procedures to be performed

Study participants will be asked to complete a questionnaire and drink 10 cc (equivalent to 2 teaspoons) of each of 3 laxatives in randomly selected order (ABC, BCA, CAB).

(A) Unflavored Polyethylene glycol electrolyte solution (unflavored golytely)

(B) Flavored Polyethylene glycol electrolyte solution (flavored golytely)

(C) Moviprep ®

This activity is voluntary but the minimum requirement for participation is to complete the questionnaire.

Why is this study being done?

This study is being done to find out if we can use the beverage intake taste preferences of volunteers to predict the bowel laxative preparations that they will tolerate. This information can be used to improve the experience of people under going colonoscopy, and hopefully, will lead to increase in uptake of colonoscopy for colon cancer screening and reduce deaths from this disease.

Participating in this study is voluntary. Your refusal to participate will not affect your care by your doctor.

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 a consent form that you agree to participate
2. Then, you will be asked to complete a questionnaire about yourself, your health and your beverage intake pattern.
3. You will be asked to drink 10cc (2 teaspoonful) of three different FDA approved bowel laxatives and you will be asked to rank them based on your preference

Initials_____

MAY 07 2012

MAY 06 2013

4. Your responses will be used to test a predictive model based on your beverage preferences, intake patterns, and your socio-demographic characteristics. Our goal is to assess our ability to correctly predict your bowel preparation taste preference.
5. The information will be recorded on paper and later transferred to computer recording.
6. 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.
7. You will receive a gift item or \$10 gift card as a token of appreciation for your involvement in this study.

How many people will be involved in the study?

There will be 800 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 questionnaire and 5 minutes to taste the 3 bowel preparation laxatives).

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. The total amount of bowel laxatives you will taste is small and is not expected to induce bowel movement or cause you to develop diarrhea. Furthermore, the 3 bowel laxatives being tasted contain the same active ingredient (polyethylene glycol) with slightly different formulations and flavoring. Therefore, we do not anticipate any additional discomfort or pain from tasting the 3 preparations as compared to tasting just one bowel preparation laxative.

Are there benefits to taking part in the study?

You will not receive a direct benefit by taking part in the study. However, the information we hope to get from this study may be helpful in making bowel preparation for colonoscopy easier for people in the future and help in preventing colorectal cancer. A benefit that you may derive personally is that you will know your own bowel preparation laxative choice should you need colonoscopy in the future.

What other options are there?

If you choose 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.

Initials _____

MAY 07 2012

MAY 06 2013

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?

You will receive a gift item or \$10 gift card 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.

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 Research Staff Member

Date

Initials _____

MAY 07 2012

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

Expiration Date

MAY 06 2013

Title: Predicting tolerability of bowel preparation laxative for colonoscopy using beverage taste preferences (Pilot clinical test phase).

Principal Investigator: Adeyinka O. Laiyemo, MD, MPH

Tests and/or procedures to be performed

Study participants will be asked to complete a baseline questionnaire about themselves and their beverage intake patterns. They will then be assigned to one of two groups.

Group1: In group 1 (intervention group), patients' beverage preferences will be analyzed based on our prediction model and will guide the choice of bowel preparation laxative recommended for the patient.

Group 2: In group 2 (usual care), the care providers will recommend the standard bowel laxative they use in their practice.

On the day of their scheduled colonoscopy, we will ask the participants to complete a short questionnaire to ascertain their experience with the bowel laxative they took.

Therefore, your participation requires completing 2 different questionnaires.

Why is this study being done?

This study is being done to find out if we can use the beverage intake taste preferences of volunteers to predict the bowel laxative preparations that they will tolerate. This information can be used to improve the experience of people under going colonoscopy, and hopefully, will lead to increase in uptake of colonoscopy for colon cancer screening and reduce deaths from this disease.

Participation in this study is voluntary. Your refusal to participate will not affect your care by your doctor.

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:

Initials _____

MAY 07 2012

MAY 06 2013

1. You will be asked to sign a consent form that you agree to participate
2. Then, you will be asked to complete a questionnaire about yourself, your health and your beverage intake pattern.
3. You will be assigned to one of the two groups described above for the choice of bowel laxative preparations that you will take for your test
4. You will be asked to fill a short questionnaire on the day of your colonoscopy to describe your experience with the bowel preparation laxative
5. The information will be recorded on paper and later transferred to computer recording.
6. 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.
7. You will receive a gift item or \$10 gift card as a token of appreciation for your involvement in this study.

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 baseline questionnaire and 5 minutes to complete the follow-up questionnaire on the day of your colonoscopy).

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 chose 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.

Are there benefits to taking part in the study?

You will not receive a direct benefit by taking part in the study. However, the information we hope to get from this study may be helpful in making bowel preparation for colonoscopy easier for people in the future and help in preventing colorectal cancer.

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.

MAY 07 2012

Expiration Date

MAY 06 2013

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 questionnaires 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?

You will receive a gift item or \$10 gift card 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 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.

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 Research Staff Member

Date

Initials _____

MAY 07 2012

Bowel Preparation Laxative Study Initial Questionnaire

Expiration Date

Dear Participant:

MAY 06 2013

Studies have shown that a high percentage of patients do not tolerate bowel preparation laxative for colonoscopy mainly because of taste. The overall goal of this study is to evaluate whether beverage intake preferences can predict bowel preparation laxative that patients may tolerate. 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 very much for your participation.

General Information – Please write in or circle the appropriate information

Today's date: _____

Last name: _____ First name _____ MI: _____

Age: _____ years

Sex: 1. Female 2. Male

Ethnicity/Race: Hispanic: 1. **Yes** 2. **No**

Non-Hispanic: 1. Black 2. White 3. Asian 4. Other

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

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

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

A. General health and lifestyle questions

Do you suffer from diabetes?	Yes	No
Do you suffer from high blood pressure (hypertension)?	Yes	No
Do you currently or recently (within 2 weeks) suffered from a cold or flu?	Yes	No
Do you have any condition that has affected your taste sensation?	Yes	No

MAY 06 2013

MAY 07 2012

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

B. Beverage intake preferences: Please circle one

Coffee intake

How do you like your coffee? Please choose one answer

- (a) I do not drink coffee
- (b) Without milk/cream; without sugar/sweetener
- (c) Without milk/cream; with sugar/sweetener
- (d) With milk/cream; without sugar/sweetener
- (e) With milk/cream; with sugar/sweetener

Tea intake

How do you like your tea? Please choose one answer.

- (a) I do not drink tea
- (b) Without milk/cream; without sugar/sweetener
- (c) Without milk/cream; with sugar/sweetener
- (d) With milk/cream; without sugar/sweetener
- (e) With milk/cream; with sugar/sweetener

Soda intake

Do you drink regular soda? Yes No

Do you drink diet soda? Yes No

Do you prefer the taste of diet soda to regular soda? Yes No

Sequence of bowel preparation tasting: **Please circle one:** 1.ABC 2.BCA 3.CAB

Please rank your bowel laxative preference: **1 = Best; 3 = Worst**

A _____ ; B _____ ; C _____

Thank you for your participation

MAY 07 2012

G_ID No: _____

1

Bowel Preparation Laxative Study Colonoscopy Questionnaire

Expiration Date

Dear Participant:

MAY 06 2013

Studies have shown that a high percentage of patients do not tolerate bowel preparation laxative for colonoscopy. The overall goal of this study is to evaluate whether beverage intake preferences can predict bowel preparation laxative that patients may tolerate. 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 very much for your participation.

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

Today's date: _____

Last name: _____ First name _____ MI: _____

Age: _____ years

Sex: 1. Female 2. Male

Ethnicity/Race: Hispanic: 1. **Yes** 2. **No**

Non-Hispanic: 1. Black 2. White 3. Asian 4. Other

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

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

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

A. General health and lifestyle questions

Do you suffer from diabetes? **Yes** **No**

Do you suffer from high blood pressure (hypertension)? **Yes** **No**

Do you currently or recently (within 2 weeks) suffered from a cold or flu? **Yes** **No**

Do you have any condition that has affected your taste sensation? **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

B. Beverage intake preferences: Please circle one

Coffee intake

How do you like your coffee? Please choose one answer

- (a) I do not drink coffee
- (b) Without milk/cream; without sugar/sweetener
- (c) Without milk/cream; with sugar/sweetener
- (d) With milk/cream; without sugar/sweetener
- (e) With milk/cream; with sugar/sweetener

APPROVED
Howard University
IRB

MAY 07 2012

Expiration Date

MAY 06 2013

Tea intake

How do you like your tea? Please choose one answer.

- (a) I do not drink tea
- (b) Without milk/cream; without sugar/sweetener
- (c) Without milk/cream; with sugar/sweetener
- (d) With milk/cream; without sugar/sweetener
- (e) With milk/cream; with sugar/sweetener

Soda intake

Do you drink regular soda? **Yes** **No**
 Do you drink diet soda? **Yes** **No**
 Do you prefer the taste of diet soda to regular soda? **Yes** **No**

Overall, how much fluid (water, soda, juice etc) do you drink per day? _____ ounces

For office use only

Signed consent: **Yes** **No** ; Randomized: **Yes** **No**
 Randomized to: 1.Usual care 2.Intervention (beverage_Laxative)

Based on beverage prediction model, patient would tolerate: 1. Unflavored golytely
 2. Flavored golytely
 3. Moviprep ®

Bowel preparation laxative issued: 1. Unflavored golytely
 2. Flavored golytely
 3. Moviprep ®
 4. None given

Thank you for your participation