Department of Veterans Affairs	VA RESEARCH CONSENT FORM **Version Date:** ***02/17/2016***		
Title of Study: **ID#**: 676769	Dietary Carbohydrate Effects on GERD in Obese Veterans: Nutritional or Hormonal?		
Principal Investigator:	Kevin Niswender, MD, PhD	**VAMC: (626)**	Tennessee Valley Healthcare System (VA TVHS)
Participant Name:		**Date:**	

PURPOSE OF THE STUDY

You are being asked to take part in a research study at the VA Tennessee Valley Healthcare System Medical Center because you have gastro-esophageal reflux disease (GERD). This study is sponsored by the VA.

The purpose of this study is to find out what effect- eating dietary carbohydrates (sugars and starches) has on acid reflux episodes, GERD symptoms and GERD medication use. Other studies have shown that diet may have a role in GERD and GERD symptoms. This study will compare how 4 diets that are different based on the amount of sugars and starches in the diet affect the amount of acid in your stomach and esophagus.

DESCRIPTION OF THE PROCEDURES AND APPROXIMATE DURATION OF THE STUDY

If you agree (or consent) to participate in this research study and have signed this informed consent document, you will be assigned at random (like the toss of a coin) to one of 4 diets with different proportions of sugars and starches, so you have an equal chance of being in any one of these diets. The only difference in the 4 groups is the diet you will follow.

We plan to enroll 200 participants. You will be given daily menus for your diet. Each day, the menu allows you 3 meals and 2 snacks. You may also be provided with some of the foods on the menus at your weekly clinic visits.

Here is a description of what we will do at each study visit:

- Baseline Visit (Today)
- Sign informed consent document
- Height and weight and waist circumference measured (using a flexible tape around your stomach area)
- Diet history: We will ask questions about all the foods and drinks that you eat each day.
- We will schedule you to come to the Vanderbilt Clinical Research Center for a DEXA (Dual Energy X-ray Absorptiometry) scan to measure your body composition (how much fat, muscle and bone you have) and to the GI clinic for pH testing at the end of study week 1. If you are a female, we will do a serum (blood) pregnancy test before the DEXA scan.
- Because of the testing we will be doing to measure the amount of acid in your stomach and esophagus, you will be asked to stop taking your GERD medications before your week 1 testing visit.

- If you are taking a medication called a proton pump inhibitor (PPI) (Prilosic, Prevacid, Aciphex, Protonix, Nexium or Zegarid]), we will ask you to stop taking it seven (7) days before your testing visits.

- If you are taking a medication called a histamine receptor antagonist (Zantac, Pepcid, Tagamet or Axid), we will ask you to stop taking it two (2) days before your testing visits.

Testing Visits: End of Study Week 1 and End of Study Week 9

- We ask you to stop eating and drinking, everything except water, at 10:00pm on the night before your scheduled week 1 and week 9 visits. We will provide you with food after your testing sessions.

- We will meet you at the VA and walk with you to the Vanderbilt Clinical Research Center (CRC) where we would like to admit you to the Vanderbilt CRC for an overnight visit, starting at 7am on the first day and ending after we remove the recording devices early the next morning. If you are unable to stay overnight, we can admit you to an outpatient room on the first day of the testing visit, but you will need to return to the medical center the next morning, and we will do the following:

- Medical history to make sure you are feeling well and do not have any current illness

- Check your vital signs (blood pressure, pulse, respiration and temperature)

- Check your weight

- Measure your waist circumference

- Blood draw: We will take about 5 teaspoons (25mls) of blood to measure glucose, insulin and hormones that are important in GERD. If you are a female, we will also do a blood pregnancy test.

- Resting Energy Expenditure: We will use a metabolic cart to measure how much energy you body expends when it is at rest for about 20 minutes. We can calculate this by measuring the oxygen your body uses to breathe in and the carbon dioxide your body produces when you breathe out. This is done by placing a large plastic hood over your head that has a tube which allows air (oxygen) in and takes air (carbon dioxide) out.

- 24 hour urine collection: On the day before the CRC visit, you will be asked to collect your urine in a jug for 24 hours to measure how effectively food is processed by the body.

- DEXA scan: This is an x-ray of your whole body to measure how much muscle, fat and bone you have. To have the DEXA scan, you will lie down on a table for 10-20 minutes.

- Diet recall: We will ask you questions about all the foods and drinks you had in the past 24 hours.

- We will also ask you questions about your GERD symptoms and medication use.

Next, we will walk with you to the Vanderbilt Digestive Disease clinic for pH Impedance Monitoring. This will include the following procedures:

- SmartPill®- The SmartPill® Motility Procedure is a convenient way of collecting information about your digestive system without radiation or an invasive test. We will ask you to swallow a capsule (like a pill) that measures the pressure, pH and temperature of your gastrointestinal tract. This information goes into a receiver that you wear around your neck. You will not have any food for 6 hours. You may have a small amount (1/2 cup) of water during this time. After 6 hours you can go back on your study diet. You will wear the receiver until you come back to the clinic in 24 hours.

- 24-hour pH monitoring: In order for the 24-hour pH test to be done, a preliminary procedure must happen before the doctor places a pH catheter in your esophagus. This first step is called manometry. Manometry will tell us the distance from your nose to the area between your esophagus and stomach (gastro-esophageal junction-GEJ). This will be done one time to allow for proper placement of the catheter. These tests cannot be done unless you have fasted prior to your appointment. Therefore, when your appointment is scheduled, you will be asked not to eat or drink anything other than water for eight (8) hours prior to your visit. During this procedure, you will be seated comfortably, and lidocaine (Xylocaine) will be sprayed into one side of your nose. This will numb and dry your throat. A narrow, soft, thin and flexible tube (about the thickness of cooked spaghetti) will be inserted through your nose, swallowed with water, and passed into your stomach. As the tube goes down your throat, you may feel like gagging or other discomfort. For example: Your eyes may water, your nose may bleed slightly, and you might salivate more than usual. In rare cases, you may cough or vomit as the tube is being placed. Positioning the tube only takes about a minute. The test should feel less uncomfortable after that. You will probably adjust quickly to the tube's presence. You will still be able to breathe normally once the tube is placed through your nose. The tube will be gently moved a little at a time to locate the GEJ.

- Then, the narrow, soft, thin and flexible catheter will be inserted through your nose, swallowed, and placed at the pre-set point in the esophagus. This step may also cause the same gagging or other discomfort as the manometry. The catheter will be taped to the side of your nose so it will not move. You will be given one pager-sized recording device which will take timed readings about the acid levels and reflux events in the esophagus. The catheter will stay in place for 24 hours. You will be instructed by the nurse on how to use the pH monitor when you eat, when you lie down to sleep, and when you get up in the morning. You will be allowed to go about your normal daily activities while the catheter is in place. You will wear this pH monitoring device for 24 hours, and then you will come back to the clinic so it can be removed.

- You might experience slight discomfort after the test. Common complications include: Minor nosebleed, sore throat and stuffy nose. These mild symptoms usually clear up within several hours.

- In rare cases, you may develop serious problems, such as perforation. This means that the tube made a hole in your esophagus.

- For these Testing Visits at the end of study week 1 and study week 9, you have the choice of staying overnight in a private room at the Vanderbilt Clincial Research Center for the 24-hour

period of testing, or you can return to the Vanderbilt Digestive Disease clinic on the morning after we start the 24-hours of pH and SmartPill monitoring so that we can remove the pH catheter and collect the recording devices.

Study Weeks 2 to 9

- During study weeks 2-9, you will follow the diet we give you.

  You will meet with the study dietitian each week.

- You may be provided with foods that will help you follow the diet each week.
- If you are unable to come in, the study dietitian will talk with you over the phone.
- During this time, we give you a notebook to keep a log each day:
  - In this notebook is a daily menu checklist so you can record the foods and drinks you have each day.
  - In this notebook there is also a medication diary so you can record the GERD medications you use each day.

Timepoint	Baseline	Day 1-7	End Wk 1	Day 8-57	Day 57-63	End Wk 9
Consent & Enrollment	X					
Randomization			X			
Bloodwork	***X***		***X***		***X***	***X***
Diet Intervention						
Off PPIs #1						
Clinical Testing #1			X			
Off PPIs #2						
Clinical Testing #2						X

VA TVHS's role in this study is to screen your medical records for GERD and process your blood samples. Your blood samples will be processed at the VA and by LabCorp. All other aspects of this study will be performed at Vanderbilt University Medical Center.

DESCRIPTION OF STUDY RELATED COSTS

You will not be required to pay for any treatment received or blood test done solely for the purpose of this research study or for any of the study-related costs. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

PAYMENT FOR PARTICIPATION/TRAVEL

You will be paid $150 at the end of each CRC visit (at the end of study weeks 1 and 9) to help compensate for the time required for all study procedures and visits. If you withdraw before the end of week 1, you will not be paid.. If you receive payment at the end of week 1 but withdraw before the end of week 9, no further payment will be made. You must agree to the release of personally identifying information such as your name, address and social security number to the VA Tennessee Valley Healthcare System to receive payment. The payment will be issued from the Austin Financial Service Center which will generate the IRS Form 1099 regardless of the amount of your compensation.

MEDICAL TREATMENT FOR RESEARCH-RELATED INJURY

Every reasonable safety measure will be used to protect your well-being. The VA will provide necessary medical treatment to you as a research participant if you are injured as a result of taking part in this study.

Compensation may or may not be available to you under applicable state and federal law in the event that you suffer physical injury or illness arising from this study. By agreeing to participate in the study you are not giving up your legal rights to seek compensation. If you have questions you may contact the VA TVHS Institutional Review Board office at 615-873-6076 or the Research and Development Service office at 615-873-8694.

COMPENSATION FOR RESEARCH-RELATED INJURY

If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS

- Following a special diet and keeping a record of what you eat and your medication use may be inconvenient.
- You will be required not to eat or drink, except water, after 10 pm on the night before your testing visits at the end of study weeks 1 and 9. This may cause you to have a headache or a feeling of weakness, or you may become irritable.
- Blood draw: Blood draws can cause redness, soreness, bleeding or bruising at the needle stick site. Some people feel faint.The CRC nurses use sterile technique and may put some cream (called EMLA) on your skin to numb the arm. The cream may make your skin change color, but this is rare.
- DEXA: Because DEXA is an x-ray, you are exposed to some radiation. The amount of radiation from the 2 DEXA scans is equal to the amount of radiation in the natural environment if you were to walk around outside for 17 days.

- Because you will not be taking your medication for GERD while you are participating in this study, it is possible that your GERD symptoms may get worse.

- 24-hour pH Monitoring:
  - Lidocaine: Lidocaine, a numbing drug, has an awful taste and causes a strange feeling in the mouth. There is a rare side effect that it may cause hoarseness and loss of voice. There is a very rare risk that it may cause problems with heart rhythm.
  - Manometry: You might experience slight discomfort after the test. Common complications include: Minor nosebleed, sore throat and stuffy nose, these mild symptoms usually clear up within several hours. In rare cases, you may develop serious problems, such as perforation. This means that the tube made a hole in your esophagus.
  - Possible risks for the participants during 24-hour study include: nasal discomfort, injury to nasal passages such as nose bleedings, allergic reaction to lidocaine gel used to numb the nasal passages for placement of tube, and rupture of the esophagus by the long tube which may require an operation.

ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

Taking part in this study may not personally help you, but you may find that the diet may reduce the amount or frequency of your GERD symptoms and you may not need to take your GERD medications as often as you have been, but there are no guarantees. The study might lead to knowledge that will help others by learning more about the effects of dietary carbohydrates on GERD and GERD symptoms.

ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE

You are not required to take part in this research study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment, if you are a patient. If you decide to stop being part of the study, you should tell your study doctor. You can choose not to take part in this research study and still take part in any other diet program.

The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study related illness or injury. You may be withdrawn from the study if laboratory tests suggest that it is not safe for you to continue.

The study doctor may withdraw you from the study if he does not think taking part is in your best interest, if you are unable to provide the information required about your diet, or if you are unable to come to the Clinical Research Center and the Digestive Disease Center for your

study test sessions at the end of week 1 and 9. If you are taken out of the study, you will be told the reason why.

RESEARCH RESULTS

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, it will include a summary of the results. You can search this website at any time.

DISPOSITION OF RESEARCH DATA AND/OR SPECIMENS

All efforts, within reason, will be made to keep your personal information in your research record confidential. Careful safeguards are in place, and confidentiality will be maintained by coding your data and blood samples using only a number to identify your data. The number assigned will be specific to this study, will not be related to other personal identifiers such as medical record number, telephone number, social security number or initials, and will only be known to the study staff. The record linking the study number with your name will be maintained by Dr. Niswender, Dr. Silver, a co-investigator and the study team. It will be kept in a locked research office and in a locked file cabinet. Computer data will be password-protected.

This research study is expected to last 5 years. It involves access of PHI date/limited data set for research as listed: Name, SSN for screening candidates (necessary for reimbursement), date(s) of lab tests and x-rays, and phone number for follow-up phone calls.

The research data will be stored at Vanderbilt University Medical Center, 1211 21st Avenue South, Medical Arts Building, Suite 514, Nashville, TN 37232 and kept in your research record in accordance with Veterans Health Administration (VHA) and Federal Records Control Schedule policies after the study is completed. Research data will be used/shared outside TVHS at the PI's office at Vanderbilt University Medical Center.

- Sensitive Research data (hard copy of signed consent form):
  - PI's office at VUMC,
- Electronic sensitive research data (computer spreadsheets and code linking to PHI)
- PI's office on VUMC Server (REDCap)
- De-identified research data (hard copy and electronic data)
  - PI's office – The data manager will use a Linux workstation, Department of Biostatistics servers, and the R Statistical Program.

CONTACT INFORMATION

If you have questions about this study, wish to express concerns or complaints about the research, or to report a research-related injury, you can contact:

Dr. Kevin Niswender by pager at (615) 835-0832 (24-hour availability). The automated voice will prompt you to enter your phone number in order for Dr. Niswender to return your call. Once you have entered your phone number, please hang up.

Dr. Heidi Silver at (615) 875-9366.

If you have general questions about giving consent or your rights as a participant in this study or wish to discuss problems or concerns, offer input, or you want to make sure this is a valid VA study, or request information you can call the VA Tennessee Valley Healthcare System (VATVHS) Institutional Review Board Office at (615) 873-6076 or the Research and Development Service Office at (615) 873-6940.You may also contact the VATVHS Patient Advocate at 1-800-228-4973, extension 67225 or 1-800-876-7093 extension 22560, or (615) 873-7225 to discuss problems or concerns and ask questions not related to the consent process, offer input, or request information.

CONFIDENTIALITY AND PRIVACY

Your rights of privacy will be maintained in the following manner. Your medical records will be maintained according to this medical center's requirements and the Privacy Act of 1974. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigators and members of the research team, and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the VA Office of Research Oversight, the VA TVHS Research Compliance Officer, the Food and Drug Administration (FDA), state regulatory authorities, and legally authorized parties.

Your permission to allow access to your medical information and a description of your rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is addressed in a separate HIPAA Authorization document. By signing the separate HIPAA Authorization form you agree to allow access, use and disclosure of your personal health information as described in the HIPAA Authorization form. By signing the consent form, you are voluntarily choosing to participate in the study as described below in this consent form.

Quick Reference Guide

VA	Veterans Affairs
TVHS	Tennessee Valley Healthcare Systems
GERD	Gastro-Esophageal Reflux Disease
DEXA	Dual Energy X-ray Absorptiometry
CRC	Clinical Research Center
pH	Measurement of acid
IRS	Internal Revenue Service
PPI	Proton Pump Inhibitor
GEJ	Gastro-Esophageal Junction

STATEMENT & SIGNATURE OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY:

Signatures. I agree to participate in this research project as described in this consent form. I will be given a signed copy of this consent form for my records. I have read or have had this consent form read to me.

- This study has been explained to me and all of my questions have been answered by the person obtaining consent. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. If I have questions later, I understand I can contact the researcher or a member of the research team.
- If I do not take part in this study, my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.
- I have been told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered.
- I will receive a copy of this consent form and a copy will be placed in my medical chart at the VA Tennessee Valley Healthcare System computerized medical record system.
- I will also receive a copy of the Department of Veterans Affairs brochure, "***Volunteering in Research: Here are some things you need to know***."

SIGNATURES: (Note: ALL signatures and dates of signature below *are required* for legally effective research consent and HIPAA authorization.)

_____
Study Participant's SSN – ***full SSN required***

_____	_____	_____
Study Participant Name (Print)	Study Participant Signature	Date
_____	_____	_____
Name of person (Print) obtaining authorization and consent	Signature of person obtaining authorization and consent	Date