# Cinnamon Trial-lIfestyle iNtervention Plus Water-soluble Cinnamon Extract On loweriNg Blood Glucose in Pre-diabetics

NCT01301521

January 24, 2018

**Volunteer Name: _____**

**WILFORD HALL AMBULATORY SURGICAL CENTER**
**INFORMED CONSENT DOCUMENT**

**Cinnamon Trial**—assessment of the effe**C**t of l**I**festyle i**N**tervention plus water-soluble ci**N**n**AM**on extract **O**n loweri**N**g blood glucose in pre-diabetics: A randomized, double-blind, multicenter, placebo controlled **TRIAL**.

**FWH20110035H**



**INFORMATION ABOUT THIS CONSENT FORM:**
You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign in more than one place in this document. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the procedures of the study and what the study is about, including the risks and possible benefits to you.

If you are taking part in another research study, please tell the researchers or study staff.



**VOLUNTARY PARTICIPATION:**
Taking part in this study is completely voluntary. You should not feel coerced or intimidated into participating in this project. You do not have to participate if you don't want to participate in the study. You do not have to participate in this study in order to get standard medical treatment. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed. If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.



**PRINCIPAL INVESTIGATOR:**
The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study is:

**Principal Investigator:**
Mike O'Callaghan Military Medical Center, Nellis Air Force Base
Col Paul Crawford, MD, USAF, MC
Phone Number: (702) 653-3298

**Study Sponsor:** The Air Force Medical Support Agency (AFMSA), a federal agency, is providing funding for this study (the sponsor). The Principal Investigator designed the study and drafted the study plan. AFMSA is providing money to the 99 Medical Group so that the researchers can conduct the study.

Integrity Nutraceuticals, a for-profit company, is funding this study (the sponsor). The Principal Investigator designed the study and drafted the study plan. Integrity Nutraceuticals provided the water-soluble cinnamon extract and placebo to the 99 Medical Group so that the researchers can conduct the study.

Your participation in this study may provide financial benefit to the corporate sponsor.

**DESCRIPTION/PURPOSE OF RESEARCH** (Why is this study being done?)**:**
You are being asked to consider participation in this research study. The purpose of this study is to see whether water-soluble cinnamon extract is effective in lowering blood glucose in patients undergoing aggressive lifestyle therapy. This study will have two groups of patients, Group 1 will take by mouth, 2 gelatin capsules that contains 1 gram of water-soluble cinnamon extract (Cinnulin PF) once a day for 1 year and then be followed for an additional 1 year plus standard of care aggressive lifestyle therapy. Group 2 will take by mouth, 2 placebo pills (gelatin capsule filled with wheat bran) once a day for 1 year, and then be followed for an additional 1 year plus standard of care aggressive lifestyle therapy. Investigators will then compare both groups to see if the use of the water-soluble cinnamon effect on fasting plasma (blood) glucose, hemoglobin A1c, lipid panel, and waist circumference.

You are being asked to consider participation in this study because you have prediabetes. People with blood glucose (sugar) levels that are higher than normal but not yet in the diabetic range have "prediabetes". People with prediabetes usually have no symptoms. You may have had prediabetes for several years without noticing anything. It is important to identify people with prediabetes because they have a higher risk of developing diabetes in the future. When you have high blood sugar over a long period of time your blood vessels in your heart, kidney, and eyes can get damaged.

Aggressive lifestyle therapy is defined as participation in any standard lifestyle intervention that your doctor refers you to as part of your routine care.

This study will enroll approximately 557 subjects at Nellis AFB. Your participation in this study will last approximately 24 months.

**PHASE III STUDY:**
This study involves the use of an investigational product called Cinnulin PF (water-soluble cinnamon extract). This means that the product has not been approved by the Food & Drug Administration (FDA) for treating or preventing diabetes. This study will help find out what effects, good and/or bad, of water-soluble cinnamon extract in lowering blood glucose. Cinnamon is supposed to be a natural insulin sensitizer, which means it helps the body return your blood sugar to normal. Insulin helps to control the amount of glucose (blood sugar) that is dissolved in the blood. Insulin prevents the blood sugar level from rising too high. The safety of this product in humans has been tested in prior research studies; however, some side effects may not yet be known.

**PROCEDURES:**
If you decide to take part in this research study, you will be asked to sign this consent form. During your participation in this study, you will be asked to make approximately 9 outpatient visits with the Principal Investigator (PI), an

Associate Investigator (AI), or study staff. It may be necessary for you to return to Nellis AFB for 24 months. As a participant, you will undergo the following procedures:

**Screening Visit:** Exams, tests, and/or procedures may be done after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Any procedure described below as "standard care" would be done even if you do not take part in this research study.



- Obtain signed Informed Consent document and HIPAA Authorization.
- We will record your date of birth, gender, race, ethnicity, name of your lifestyle intervention for pre-diabetes, current email address, height (in inches), weight (in pounds), waist circumference measurement (in inches), blood pressure, and whether you are taking any statins, fibrate, niacin or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- If you are capable of becoming pregnant, you will have a serum pregnancy test done (approximately 5-10 milliliters (mls), 1-2 teaspoons of blood) (research-driven).
  - You will have the following blood tests:
    - Fasting comprehensive metabolic panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

    *If you've had a fasting comprehensive metabolic panel test within the 2 weeks before Visit 1, you will not have to have this test again.
    - Hemoglobin A1C via 1 venipuncture (5-10 milliliters (mls) approximately 1-2 teaspoons of blood) (research-driven).

    *If you've had a Hemoglobin A1c test within the 2 weeks before Visit 1, you will not have to have this test again.
    - Lipid panel via 1 venipuncture (5-10 milliliters (mls) approximately 1-2 teaspoons of blood) (research-driven).

    *If you've had a lipid panel test within the 2 weeks before Visit 1, you will not have to have this test again.



This screening visit will take approximately 30 minutes. The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options.



**Visit 1 (Day 1-within 30 days of Screening Visit):**

- We will record whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- You will be asked to complete the Rand 36-Item Health Survey.
- You will be randomly assigned (like flipping a coin) to 1 of 2 groups (research-driven):
  **Group 1**: Will take by mouth, 2 gelatin capsules that contain 1 gram water-soluble cinnamon extract (Cinnulin PF) once a day for 1 year, then be followed for 2 years plus standard of care aggressive lifestyle therapy*.*
  **Group 2**: Will take by mouth, 2 placebo pills (gelatin capsule filled with wheat bran) once a day for 1 year,

then be followed for 2 years plus standard of care aggressive lifestyle therapy.

- You will be provided a pill container to assist with remembering to take your study pills and a bathroom scale to weigh yourself.
- You will be given a Study Diary that you will bring with you and give to the Research Staff at next study visit.
- You will be told to fast (not eat or drink anything) for at least 10 hours prior to Visit 2.

**Visit 2-Month 3 (90 days after Visit 1):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data (research-driven).
- You will bring in any remaining study pills and give to the research staff.
- We will collect your Study Diary and issue you a new Study Diary.
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 3.
- We will refill your study pills at this visit (research-driven).
- You will have the following standard of care blood tests:
  - Fasting comprehensive metabolic panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

  *If you've had a fasting comprehensive metabolic panel test within the 2 weeks before Visit 2, you will not have to have this test again.
  - Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

  *If you've had a Hemoglobin A1c test within the 2 weeks before Visit 2, you will not have to have this test again.
  - Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

  *If you've had a lipid panel test within the 2 weeks before Visit 2, you will not have to have this test again.

**Visit 3-Month 6 (90 days after Visit 2):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data (research-driven).
- You will bring in any remaining study pills and give to the research staff.
- We will collect your Study Diary and issue you a new Study Diary.
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 4.
- We will refill your study pills at this visit (research-driven).
- You will have the following research-driven blood tests:
  - Fasting comprehensive metabolic panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons).

  *If you've had a fasting comprehensive metabolic panel test within the 2 weeks before Visit 3, you will not

have to have this test again.
- ○ Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons).

*If you've had a Hemoglobin A1c test within the 2 weeks before Visit 3, you will not have to have this test again.
- ○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons).

*If you've had a lipid panel test within the 2 weeks before Visit 3, you will not have to have this test again.

**Visit 4-Month 9 (90 days after Visit 3):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data (research-driven).
- You will bring in any remaining study pills and give to the research staff.
- We will collect your Study Diary and issue you a new Study Diary.
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 5.
- We will refill your study pills at this visit (research-driven).
- You will have the following standard of care blood tests:
  - ○ Fasting comprehensive metabolic panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

  *If you've had a Fasting comprehensive metabolic panel test within the 2 weeks before Visit 4, you will not have to have this test again.
  - ○ Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

  *If you had a Hemoglobin A1c test within the 2 weeks before Visit 4, you will not have to have this test again.
  - ○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

  *If you've had a lipid panel test within the 2 weeks before Visit 4, you will not have to have this test again.

**Visit 5-Month 12 (90 days after Visit 4):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data. (research-driven)
- You will be asked to complete the Rand 36-Item Health Survey.
- You will bring in any remaining study pills and give to the research staff.
- We will collect your Study Diary.
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 6.
- You will have the following research-driven blood tests:
  - ○ Fasting comprehensive metabolic panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).

*If you've had a Fasting comprehensive metabolic panel test within the 2 weeks before Visit 5, you will not have to have this test again.

- ○ Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
  *If you've had a Hemoglobin A1c test within the 2 weeks before Visit 5, you will not have to have this test again.
- ○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
  *If you've had a lipid panel test within the 2 weeks before Visit 5, you will not have to have this test again.

**Visit 6-Month 15 (90 days after Visit 5):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data (research-driven).
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 7.
- You will have the following standard of care blood tests:
  - ○ Fasting comprehensive metabolic panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
    *If you've had a Fasting comprehensive metabolic panel test within the 2 weeks before Visit 6, you will not have to have this test again.
  - ○ Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
    *If you've had a Hemoglobin A1c test within the 2 weeks before Visit 6, you will not have to have this test again.
  - ○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
    *If you've had a lipid panel test within the 2 weeks before Visit 6, you will not have to have this test again.

**Visit 7-Month 18 (90 days after Visit 6):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data (research-driven).
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 8.
- You will have the following research-driven blood tests:
  - ○ Fasting plasma glucose via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
    *If you've had a fasting glucose test within the 2 weeks before Visit 7, you will not have to have this test again.
  - ○ Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
    *If you've had a Hemoglobin A1c test within the 2 weeks before Visit 7, you will not have to have this test again.

○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
*If you've had a lipid panel test within the 2 weeks before Visit 7, you will not have to have this test again.

**Visit 8-Month 21 (90 days after Visit 7):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data. (research-driven)
- You will be told to fast (not eat or drink anything, except water) for at least 10 hours prior to Visit 9.
- You will have the following standard of care blood tests:
  ○ Fasting plasma glucose via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons)
  *If you had a Fasting Glucose test within the 2 weeks before Visit 8, you will not have to have this test again.
  ○ Hemoglobin A1C via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons)
  *If you had a Hemoglobin A1C test within the 2 weeks before Visit 8, you will not have to have this test again.
  ○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons)
  *If you had a Lipid Panel test within the 2 weeks before Visit 8, you will not have to have this test again.

**Visit 9-Month 24 (90 days after Visit 8):**

- We will record your weight (in pounds), waist circumference measurement (in inches), blood pressure, verify current email address, and whether you are taking any statins, fibrate, niacin, or bile acid binding agents. If yes, we need the name of drug, strength, and dose.
- You will be asked to complete the Rand 36-Item Health Survey.
- We will ask you if you have had any side effects to report including cardiovascular procedures and events and other morbidity data (research-driven).
- You will have the following research-driven blood tests:
  ○ Fasting plasma glucose via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
  *If you've had a fasting glucose test within the 2 weeks before Visit 9, you will not have to have this test again.
  ○ Hemoglobin A1c via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
  *If you've had a Hemoglobin A1c test within the 2 weeks before Visit 9, you will not have to have this test again.
  ○ Lipid panel via 1 venipuncture (5-10 mls, approximately 1-2 teaspoons of blood).
  *If you've had a lipid panel test within the 2 weeks before Visit 9, you will not have to have this test again.

Your participation in this study is completed after Visit 9. Research has shown that cinnamon is effective in lowering hemoglobin A1c levels. Taking water soluble cinnamon extract does not increase the risks to most patients as cinnamon is a food additive and also a dietary supplement sold over the counter.

**Assignment to Study Groups**: When it is determined that you are eligible for the study, you will be assigned by chance

(like flipping a coin) to 1 of 2 study groups. One group will have their standard of care diabetes treatment of aggressive lifestyle therapy plus placebo. The second group will have water-soluble cinnamon extract (Cinnulin PF) plus aggressive lifestyle therapy to see how it affects fasting glucose, hemoglobin A1c, lipid panel and waist circumference. You will have a one in 2 chance of being in the placebo group. A placebo is an inactive, harmless substance that looks like the water soluble cinnamon extract (Cinnulin PF). Neither you nor the researchers will know whether you are receiving standard treatment with placebo or water-soluble cinnamon extract. In the event of an emergency, there is a way for the researcher to find out which you are receiving.

**RISKS OR DISCOMFORTS: Risks from the specific research procedures (drug(s), interventions, or procedures)**
There are risks to taking part in this research study. One risk is that you may have side effects while on the study. Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely). Side effects from this study will usually go away soon after you stop taking the water-soluble cinnamon extract (Cinnulin PF). The side effects related to the blood draw will usually go away soon after the blood draw has been completed. In some cases, side effects can be long lasting or may never go away. Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.



The following section will describe the risks related to each drug, intervention, or procedure that is part of this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study. Risks and side effects related to the water-soluble cinnamon extract (Cinnulin PF) include those which are:

**Less likely and not serious**

- **Hypoglycemia** (low blood sugar):
  - Heart palpitations (abnormal heart beats either fast or slow)
  - Tremors (involuntary muscle movement)
  - Hunger
  - Sweating

*If you experience any of these symptoms, you should eat 15-20 grams of sugar (for example glucose (sugar) tablets, glass of juice or other snack containing sugar), then eat some carbohydrates (for example a small meal or cracker with peanut butter).



**Less Likely and serious**

- **Cinnamon and Wheat Bran**: There may be a risk that you have an allergy to cinnamon or wheat bran that you are not currently aware of. The signs and symptoms of an allergic reaction include:
  - Shortness of breath
  - Hives (itchy rash)
  - Runny nose
  - Watery eyes

- Sore eyes
- Asthma
- Lip swelling
- Tongue swelling
- Nausea
- Brochospasm (a bronchial spasm is a sudden constriction of the muscles in the walls of the bronchioles)
- Anaphylaxis (whole-body allergic reaction that has the following signs and symptoms):
  - Abdominal pain or cramping
  - Abnormal (high-pitched) breathing sounds
  - Anxiety
  - Confusion
  - Cough
  - Diarrhea
  - Difficulty breathing
  - Difficulty swallowing
  - Fainting, light-headedness, dizziness
  - Hives
  - Itchiness
  - Nasal congestion
  - Nausea, vomiting
  - Palpitations
  - Skin redness
  - Slurred speech
  - Wheezing

*If you experience any of these symptoms, stop taking the study medication and seek urgent medical treatment.



**Rare and Serious:**

- **RAND-36 item Health Questionnaire**: Risks and side effects related to the RAND-36 item Health Questionnaire include those which are:
  - There is a risk (although rare) that the questionnaire may identify you as at risk for a mental health condition and result in a referral to mental health. Occasionally a person diagnosed with a mental health condition may be disqualified from active duty and a Medical Evaluation Board (MEB) referral is made.

There is also a risk of accidental release of confidential information. Cinnamon is a nutritional supplement and is generally regarded as safe for human consumption by the Food and Drug Administration (FDA). The water-soluble cinnamon extract under investigation in this study has not shown to cause birth defects. For more information about risks and side effects, ask one of the researchers or study staff.

As a FEMALE OF CHILDBEARING POTENTIAL wishing to volunteer for this project, you must not be pregnant and agree to take a pregnancy test before you participate in this study. You must also agree to take precautions to prevent pregnancy during the course of this study. The only completely reliable methods of birth control are total abstinence

or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. Also, you may not breast-feed and participate in this study. If you become pregnant or feel you might be pregnant, contact your provider and the study investigator listed in the voluntary participation section.

**Are there risks if you also participate in other research studies?** Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers. There may also be unforeseen risks associated with this or any research study. We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.



**WITHDRAWAL FROM THE STUDY:**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled.

**ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY?**

If you decide to withdraw from this study early, please discuss your decision with the Principal Investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.



**ADDITIONAL CIRCUMSTANCES OF WITHDRAWAL:** The researcher may withdraw you from the study prior to the study's end and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the researchers and study staff.
- The researcher decides that continuing your participation is not in your best interests.
- You become ineligible to participate.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.
- If you experience an allergic reaction to the study medication.



Should you be withdrawn from the study by the Investigator or study sponsor, the Investigator will refer you to your primary care provider. If you lose your status as a military health care beneficiary, you can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation. The sponsor of this study may terminate the study and/or your participation in this study for safety reasons or if the drug receives FDA approval. There is no guarantee that the drug you received during this study will continue to be available through the military system.

**BENEFITS:**

The investigators have designed this study to learn if the water-soluble cinnamon extract is as good as or better than or worse in lowering blood glucose in patients undergoing aggressive diabetic lifestyle therapy. However, there is no guarantee or promise that you will receive any benefit from this study other than knowing that the information may help future patients. The possible benefits of your participation in this study are that your hemoglobin A1c blood levels and your long term health may improve by decreasing your risk of developing diabetes.

**COSTS: Will taking part in this study cost anything?**

The investigators have designed this study so that there is no cost to you to participate in this study other that what it will cost you to travel to the research appointments. The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care is governed by federal laws and regulations.



**PAYMENT (COMPENSATION):**

You will not receive any compensation (payment) for participating in this study.

**ALTERNATIVES TO PARTICIPATION:**

Choosing not to participate in this study is your alternative to volunteering for the study.



**CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:** Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement – Military Health Records, contains the Privacy Act Statement for the records.This is to inform you this study meets the definition of an applicable clinical trial under Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), which requires responsible parties to register and submit summary results of applicable clinical trials with ClinicalTrials.gov. The law applies to certain clinical trials of drugs (including biological products) and medical devices. As a condition for the publication of research results generated by the clinical trial, the International Committee of Medical Journal Editors (ICMJE) also requires trial registration through ClinicalTrials.gov. The NCT number, NCT01301521, also called the ClinicalTrials.gov Identifier, can be used to obtain additional information about the registration of the clinical trial.



By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, or the WHASC Institutional Review Board.

A copy of this consent will be placed in your medical and/or research record. A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. Information collected on this study about you that will affect your medical care will be placed in your medical record. Your medical record will be annotated to reflect you are participating in a research study. All information about you collected on this study will be kept in an electronic database, which will be double password-protected, firewall-protected and

access-restricted to people involved in this study. As soon as possible, any link between your identity and the research information will be destroyed. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent. The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.



**ENTITLEMENT TO CARE:**

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors. In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Wilford Hall Chief, Clinical Research, (210) 292-7069 or the WHASC Risk Manager, (210) 292-6004, or at the facility that enrolled you in this study:



- Mike O'Callaghan Military Medical Center Human Subject Protection Contact, (702) 653-3298

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

**BLOOD, TISSUE & BIOLOGICAL SAMPLES:**

All blood samples kept at Nellis AFB will be handled and disposed of in accordance with federal regulations. Laboratories outside of these medical sites will not have permission to use the samples for any additional research.



**PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA:**

All PHI and PII data that will be used in the database repository will be kept at the Mike O'Callaghan Military Medical Center (Nellis AFB), Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of Nellis AFB will have access to this database without permission of the Database Repository, Manager Col Paul Crawford, and the Wilford Hall Ambulatory Surgery Center (WHASC) Institutional Review Board (IRB).

The Investigators are asking for your permission to store your PHI and PII in the database repository for future use in research studies. The specifics of these research studies are unknown at this time, but these studies will frequently be in the areas of diabetes and preventative care. Your stored PHI and PII will be information such as gender, birth date, age, height/weight, medical history, laboratory tests, blood pressure, waist circumference

measurements and surgical procedures and post-surgery outcomes. This data is considered both identifying and non-identifying information and may be traced back to you as a donor when added to a database. The Principle Investigator and Database Repository Manager will take every precaution possible to safeguard your information to eliminate the possibility of any breach of confidentiality. This is explained below in the section, "Confidentiality". The Database Repository Manager, Col Paul Crawford, is responsible for all PHI and PII data stored in the repository. All recipient investigators requesting data from the repository must have approval from the Database Repository Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and the WHASC IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information can't be traced back to the donor of the data. Recipient investigators may only receive limited data sets of de-identified information necessary to conduct their research. Generally, you will not be provided with the results of these research studies using your de-identified data from the repository. Any results would be of unclear value and unknown clinical meaning, since your de-identified data will be combined with other de-identified data from numerous patients used for the study.



You may request that your PHI and PII data be withdrawn from the database repository at any time, if you decide you no longer want to participate. This request may be accomplished by calling the Database Repository Manager at Col Paul Crawford or mailing your request to the following address: Col Paul Crawford, MD, c/o Department of Medical Education, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.



_____NO: I do not authorize the storage of my PHI and PII data for future use in research studies.

_____YES: I authorize the storage of my PHI and PII data for future use in research studies.

_____

Signature of Study Participant



**CONTACT INFORMATION:**

The Principal Investigator or a member of Nellis Family Medicine Residency staff will be available to answer any questions concerning procedures throughout this study.

**Principal Investigator:**

Mike O'Callaghan Military Medical Center, Nellis Air Force Base
Col Paul Crawford, MD, USAF, MC
Phone Number: (702) 653-3298

Institutional Review Board (IRB): The WHASC Institutional Review Board (IRB), the hospital committee responsible for safeguarding your rights as a research subject, has assigned a member of the IRB, who is not part of the study team, to serve as an outside monitor for this study (this person is the Research Monitor). If you have any questions about your rights as a research subject, research-related injuries or any other concerns that cannot be addressed by the PI, you can contact the research monitors Maj David Moss (Primary) or Capt Matthew Hawks at (702) 653-3298. Or mail

to: Clinical Investigation Program, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the WHASC IRB at (210) 916-8251. Or mail to: 59th Medical Wing/CMO, 1100 Wilford Hall Loop, Lackland Air Force Base, TX 78236. Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

**SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:**

- You have read the above information.
- Your questions have been answered to your satisfaction.

A signed copy of this form has been given to you.



_____ _____

**VOLUNTEER'S SIGNATURE** **DATE**



_____

**VOLUNTEER'S PRINTED NAME**

_____ _____ (____)_____-_____

**ADVISING INVESTIGATOR'S SIGNATURE** **DATE** **PHONE#**



_____

**PRINTED NAME OF ADVISING INVESTIGATOR**

_____ _____

**WITNESS' SIGNATURE** **DATE**

(Must witness ALL signatures)

_____

**PRINTED NAME OF WITNESS**

**For Protocol Office Use Only:**
FWH20110035H, ICD, Crawford, AMD 27

**Version: 1 Dec 12**