IRB NUMBER: 204197081512

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
MARCELLA NIEHOFF SCHOOL OF NURSING

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Sunshine 2 Study for Women with Diabetes

THE APPROVAL FOR THIS PROJECT EXPIRES ON 05/17/2018.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF RESEARCH: You are being asked to participate in this study because you have diabetes. There is evidence to indicate that women with diabetes are more likely to have symptoms of depression. Depression can impact the manner in which you are able to manage your diabetes. There is evidence to suggest that vitamin D supplementation in healthy persons is associated with an improvement in mood.

Because women with diabetes who have depressive symptoms are at risk for poor self-management, this study will examine whether vitamin D supplementation improves mood and whether this change in mood can help you to better care for your diabetes.

Some observational studies have suggested that vitamin D may help to lower systolic blood pressure. As a result, blood pressure is also being examined.

Finally, since evidence suggests that depression is associated with inflammation, and vitamin D supplementation may help to decrease inflammation, we will study inflammatory and vascular markers in your blood. We will also study inflammatory markers and potential bacteria in your urine to see if they improve when taking vitamin D.

This purpose of this study is to find out if vitamin D supplementation will improve depressive symptoms, self-management, and blood pressure. If vitamin D supplementation decreases inflammation and subsequently improves depression is also being explored.

This research is sponsored by National Institute of Nursing Research

Approximately 180 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will be randomly assigned, like the flip of a coin, to receive either 50,000 IUs of vitamin D_3 weekly or 5000 IUs of vitamin D_3 weekly. You will not be told which dose of vitamin D you will receive and you will not be able to choose which group you will be assigned to. The 50,000 IUs of vitamin D_3 weekly is the study dose and 5000 IUs approximates the standard dose of vitamin D currently recommended by the Institute of Medicine in a given week. Bio Tech Pharmacal, Inc. will be supplying the study supplements.

Your chances of being assigned to either or any of the treatments are equal.

If you agree to participate, you will be asked to come to Loyola for four visits to collect information needed for the study. The first visit will be for screening and data collection. The second visit will be for having a body composition scan and receiving the study supplement with instructions on how to take it. The last 2 visits will be follow-up visits (3 and 6 months) after starting your supplement.

When comprehensive data is collected (baseline screenings, 3 and 6 months follow-ups), the baseline visit will last between 2 and 3 hours and subsequent visits will last between 1 to 2 hours. At these visits, you will be asked to:

(1) complete questionnaire booklets that ask questions about your feelings, management of your diabetes which includes how your family may impact on your ability to manage your diabetes and mood as well as symptoms related to diabetes (e.g., urinary, sleep). We will also study factors that can impact your vitamin D level like sun exposure and diet.
(2) have physical measurements taken such as height, weight, and blood pressure,

(3) have blood drawn (about 6 teaspoons) for tests that will tell us about your vitamin D and factors that impact on your vitamin D (parathyroid hormone, calcium). We will also assess your diabetes (HBA1c, blood sugar), inflammatory and vascular factors, and a metabolic profile (e.g., kidney function-creatinine).
(4) have urine collected (about 8 tablespoons) for examination of potential bacteria and inflammatory markers.
(5) complete a verbal interview that asks specific questions about your emotional well being at baseline, 3 and 6 months follow-up.
(6) have a physical exam upon entry into study and at completion of the study
(7) complete a body composition scan (which includes bone, lean, and fat mass) to assess after your baseline visit and before you begin your weekly vitamin D.
(8) phone calls during and following the study as needed.

You will be asked to take a capsule (either 50,000 IUs D3 or 5000IUs D_3) once a week for six months. Once a week you will receive a message to remind you to take your capsule (preferred method of text, e-mail or phone) and to call us if any questions or concerns at 708-216-9303.

Your HBA1c will be measured by a fingerstick in our office. Your blood sugar, vitamin D, parathyroid hormone, calcium, and metabolic profile will be sent to a laboratory. Inflammatory and vascular factors will be measured in a research laboratory. The vitamin D and blood sugar test results will be given to you after the study has ended.

Optional Biobanking: You may optionally agree to allow us to collect and store approximately two tablespoons of blood collected and eight tablespoons of urine from you at the study visits. This blood will be coded and paired with coded clinical data for future research purposes. We will ask you to sign a second, separate informed consent document if you agree to bank samples for future research. You do not need to agree to the collection and storage of your blood in order to participate in this study.

RISKS/DISCOMFORTS: It will be important that you do not take other vitamin D supplements while in this study as you may be taking 50,000 IU weekly of D_3. Published reports suggest that 50,000 IUs per day of vitamin D (note that the proposed study dose is 50,000 IU per week) can increase vitamin D and cause high calcium levels, this is called hypercalcemia. We will be checking your calcium level at the blood draw visits to evaluate if you have hypercalcemia. The current dose for this study is one capsule of 50,000 IU per week which equates to about 7000 IU per day.

The dose at which the Vitamin D is being administered has minimal side effects. Side effects most commonly reported include: bone pain, constipation, dry mouth, headache, nausea, and vomiting. Since vitamin D may increase serum calcium, there is the potential to develop kidney stones. If you are unsure if you should participate in the study, you should speak with your doctor first. We will be monitoring for side effects upon your study visits and with phone calls.

It is important that you understand that if you need assistance with the management of your

emotions such as medication or counseling, you should talk to your health care provider about this. If we assess that you have thoughts of harming yourself during the study, our study staff. Angelos Halaris or Dr. Patricia Mumby will be contacted as well as your health care provider. Signing this consent document will give us permission to contact your health care provider if that situation should arise. If you do not have a health care provider, we can provide a list for you.

DXA will be used to measure body composition. There is radiation exposure with a DXA scan which is about 12microSieverts. The amount is less than the radiation absorbed by a passenger on a roundtrip transcontinental flight (about 60 microSieverts).

You may experience a slight discomfort when the blood is drawn for lab tests.

Because the urine is being examined for bacteria in a research laboratory, we will not be able to provide you results of this test. However, if you have symptoms of a urinary tract infection, you should speak to your healthcare provider.

In addition to the risks mentioned above, there may be unknown or unanticipated risks associated with participating in this study.

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are pregnant or breast feeding.

If you are a woman of childbearing potential, a pregnancy test will be done to make certain that you are not pregnant before beginning the study because of the vitamin D supplementation and the test for body composition.

Women who are able to have children must use an effective method of preventing pregnancy while participating in this study.

In addition, as study medications may remain in the body for a period beyond their administration, you will be asked to continue to employ an effective method of preventing pregnancy for six months after you have finished taking the study medication.
You are encouraged to discuss your preferred method with your doctor. Your doctor will answer any questions you have regarding effective methods of preventing pregnancy. It is important that you consult with your physician because some study medications may affect the effectiveness of various methods of preventing pregnancy.

You must notify the study staff you become pregnant or suspect that you have become pregnant during your participation in this study.

BENEFITS: We do not know if you will benefit from participating in this study. The information we learn may help others in the future.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project.

FINANCIAL INFORMATION: Neither you nor your insurance provider will be billed for any procedures that are performed exclusively for this research study. The vitamin D_3 supplementation will be provided free of charge.

You will be compensated for your time. There will be a maximum of $115 for your participation. This will be $25 for the baseline visit 1, $25 for baseline visit 2, $30 for the 3 month visit and $35 for the 6 month visit. Your parking will be paid at every visit.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, you will be referred to your doctor to take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Loyola University Health System or Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center (LUMC) medical records. The information will be collected by the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University Chicago; the research sponsor; data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

In this way, we will learn about Vitamin D and its relationship to depression, diabetes, and self-management.

The information we will collect and send includes:

X DEMOGRAPHIC INFORMATION (e.g., name, address, phone number, Social Security Number)

X BLOOD AND URINE SAMPLES

X SURVEYS

X BODY COMPOSITION

We will collect and provide this information about you for as long as you are in the study.

Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the sponsor, National Institute of Nursing Research, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to LUMC and view the medical record (see above for description of

content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

For your safety, we may ask that you return to clinic one more time for laboratory tests if the supplement is discontinued by the study physician. We will also ask that you return any unused study medication.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Sue Penckofer, PhD, RN or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, National Institute of Nursing Research, may terminate the study at any time with or without your consent.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-9303.

_____Date:____/_____/____
Signature

Sue Penckofer, PhD, RN, the principal investigator for this study, or associates will be available to answer any questions you may have. Sue Penckofer can be reached at: 708-216-9303.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or the Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/____
Signature: Witness

PROJECT TITLE: Sunshine 2 Study for Women with Diabetes

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Sunshine 2 Study for Women with Diabetes", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Sue Penckofer, PhD, RN
School of Nursing
Loyola University Chicago
Building 105, Room 4529
2160 South First Avenue
Maywood, Illinois 60153