## Informed Consent to Participate in a Research Study

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| **Title of the Project:** | **Treatment of Vitamin D deficiency with large bolus cholecalciferol in the outpatient setting** |
| **Protocol Number:** | |
| **Sponsor:** | **Parkview Medical Center** |
| **Principal Investigator:** | Stephanie Franquemont, DO, BS/BA<br>311 W 14th St<br>Pueblo, CO 81003<br>Parkview Medical Center, Graduate Medical Education |
| **Study Related Phone Number(s)** | Parkview Adult Medicine Clinic<br>719/595-7585 |
| **Co-investigator:** | Kourtney Aylor, DO, BS, Parkview Medical Center, Graduate Medical Education |
| **Co-investigator:** | Vincent Vaughn, DO, BS, Parkview Medical Center, Graduate Medical Education |

## Invitation to Participate in a Research Study

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject. If you are a legally authorized representative, please remember that "you" means research (study) subject.

## Summary

You are being asked to be in a research study because you have vitamin D deficiency. The purpose of this consent form is to help you decide if you want to be in the research study. If you join the study, you will be assigned to one of two treatment groups – either taking a one-time large dose of vitamin D or daily smaller doses of vitamin D. The group taking smaller doses daily is the current standard treatment for vitamin D deficiency. We will be comparing how effective the experimental dose is compared to the standard treatment.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is treatment normally given for a certain condition or illness.

## Purpose of the Study

We are looking to compare the treatment of vitamin D deficiency with a single, large dose of vitamin D as compare to a traditional daily treatment regimen. We will look at vitamin D levels shortly after starting treatment and then every three months for one year.

## How long will the research last?

We expect that you will be in this research study for 1 year.

## How many people will be studied?

We expect about 100 people will be in this research study.

## Description of Your Involvement

If you agree to be part of the research study, we will ask you to take the study medicine as directed and to come to the Parkview Adult Medicine Clinic on six different occasions over the course of a year for study visits. You will have a 50% chance of being randomly assigned to the high-dose group vs the standard treatment group. Below is information about each visit:

**Visit 1 (Day 1):**

- Informed consent -- We will go over the procedures, benefits, risks, and answer any questions you may have about the study. You can withdraw from the study at any time, even after signing the consent form.
- Screening questionnaire -- We will go through a screening questionnaire to ensure that you meet all criteria for enrollment in the study.
- Blood draw -- A blood draw will be done to establish baseline levels prior to starting the experiment.
- After this visit, you will be randomly assigned to a treatment group. You will be called by one of the investigators to inform you of which group you will be in. A prescription will be sent for that medication to The Pharmacy at Parkview. You will start this medication the morning after picking it up unless you get it on Friday or Sunday in which case you will start on Monday.

**Visit 2 (Day 7):**

- Follow-up questionnaire -- one week after starting the study medications, we will have you return to go through a questionnaire specifically about the time since starting the medications.
- Blood draw -- a blood draw will be done to check your renal function, electrolytes, and vitamin D level one week after starting treatment.

**Visit 3 (3 months):**

- Follow-up questionnaire -- three months after starting the study medications, we will have you return to go through a questionnaire specifically about the time since starting the medications.
- Blood draw -- a blood draw will be done to check your renal function, electrolytes, and vitamin D level three months after starting treatment.

**Visit 4 (6 months):**

- Follow-up questionnaire -- six months after starting the study medications, we will have you return to go through a questionnaire specifically about the time since starting the medications.
- Blood draw -- a blood draw will be done to check your renal function, electrolytes, and vitamin D level six months after starting treatment.

**Visit 5 (9 months):**

- Follow-up questionnaire -- nine months after starting the study medications, we will have you return to go through a questionnaire specifically about the time since starting the medications.
- Blood draw -- a blood draw will be done to check your renal function, electrolytes, and vitamin D level nine months after starting treatment.

**Visit 6 (12 months):**

- Follow-up questionnaire -- twelve months after starting the study medications, we will have you return to go through a questionnaire specifically about the time since starting the medications.
- Blood draw -- a blood draw will be done to check your renal function, electrolytes, and vitamin D level twelve months after starting treatment.

## Reasonably Foreseeable Risks or Discomforts to the Subjects

We do not anticipate significant risks to participation in this study. The medications we are using have been studied previously and been found to be safe and well tolerated; even at the larger experimental dose.

The major risk to participants is the possibility of high calcium levels as a result of the vitamin D taken. Symptoms of hypercalcemia are not specific to that condition and may include: fatigue, muscle weakness, decreased appetite, dehydration, increased thirst, confusion, constipation, or nausea/vomiting. The risk of this is greatest 7-14 days after starting the medication and wanes after that. We will be checking labs in that time frame to make sure you do not have side effects of high calcium levels.

You will undergo blood draws periodically through this experiment. The risks are unlikely but do include unintentional bleeding, bruising, hematoma, or infection. There is also risk of lightheadedness and dizziness after the blood draw

There may be side effects that are not known at this time.

Your condition may not get better or may get worse during this study.

## Significant New Findings

You will be told about any significant new findings developed during the course of the research, which may relate to your willingness to continue. You may be asked to sign a new informed consent form if this occurs.

## Benefits of Participation

You may directly benefit from being in this study because of treatment of your vitamin D deficiency. There are many parts of your health may be affected by vitamin D deficiency and could be treated during this study. At the same time, many of the effects may be subtle and you may not notice any changes with treatment. Your participation may help others in the future who may benefit from the proposed large, single dose of vitamin D.

## Costs

You will not have to pay out-of-pocket for any of the medications or lab costs associated with this study. You will not have to pay for any of the study visits.

The only cost for you will be responsible for will be for transportation to and from your visits.

## Compensation for Participation

For your participation in this research project, you will receive no monetary compensation.

## Alternate Treatment

If you decide not to enter this study, there are other choices available. These include different options for formulations and dosing of vitamin D replacement. Ask your doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

## Authorization to Use and Disclose Information for Research Purposes

Efforts will be made to limit the use and disclosure of your personal health information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

What information may be used and given to others:
The study doctor will get your personal health and medical information. For example:

- To go for the research
- To study the results,
- To see if the research was done right,
- Past and present medical records,
- Research records,
- Records and phone calls made as part of this research, and
- Records about your study visits.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Parkview Institutional Review Board,
- Western Institutional Review Board,
- Governmental agencies in other countries,

If the results of this study are made public, information that identifies you will not be used.

If you decide not to give permission to use and give out your information, then you will not be able to be in this research study.

You may review or copy your information only after the research is over.

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

## Confidentiality

We plan to publish the results of this study. We will not include any information that would identify you. Your privacy will be protected and your research records will be confidential.

It is possible that other people may need to see the information you give us as part of the study, such as organizations responsible for making sure the research is done safely and properly, like the Parkview Medical Center Institutional Review Board or government offices.

## Storage and Future Use of Data

We will store your data to use for future research studies. Your name and any other identifying information will be secured and stored separately from your research data at the Parkview Adult Medicine Clinic. Only Dr. Franquemont, the Principal Investigator, will have access to your research files and data. Research data may be shared with other investigators but will never contain any information that could identify you.

## Voluntary Participation and Withdrawal

Participating in this study is completely voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to Dr Stephanie Franquemont. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- If it is in your best interest
- If you do not consent to continue in the study after being told of changes in the research that may affect you
- If you do not start the study medications
- If you become pregnant

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

## Compensation for Injury

If you are injured or get sick as a result of being in this study, call Dr Stephanie Franquemont immediately at 719/595-7585. The study doctor will coordinate emergency medical treatment. Your insurance will not be billed for this treatment. No other payment is routinely available from the study doctor or sponsor.

## Questions

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact Dr. Stephanie Franquemont at the Parkview Adult Medicine Clinic, 719/595-7585.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the:
Parkview Medical Center Institutional Review Board
400 West 16th Street
Pueblo, Colorado 81003
Telephone: (719) 584-4855
Email: greg_harder@parkviewmc.com
Parkview IRB is a group of people who independently review research.
Do not sign this informed consent form unless you have had a chance to ask any questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this informed consent form for your records.

## Consent

By signing this document, you are agreeing to be in the study. I/we will give you a copy of this document for your records. I/we will keep one copy with the study records. Be sure that I/we have answered any questions you have about the study and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

*I agree to participate in the study.*

_____
Printed Name

_____
Signature Date