Research Subject Information Sheet

Sponsor: GrassrootsHealth

Protocol Title: 25-hydroxyvitamin D [25(OH)D] serum levels and associated health outcomes in the population resulting from a program of education and testing

Investigator: Dr. Cedric Garland

The purpose of this population study is to offer testing and/or feedback about results and education to make necessary lifestyle changes to effect serum level concentrations. In this study you will create an account with GrassrootsHealth (GRH), fill out a health questionnaire and receive vitamin D test results either from a home blood spot test provided by GRH or from a participating GRH Certified physician and lab (available only to participants of qualifying GRH projects). For the home blood spot test, you will provide drops of blood on the blood spot card and return it to GRH. The results of the test will be made available to you through the account created on the GRH website along with information about target levels. The test results are strictly informational. The review of your test requests by the study investigator does not represent diagnosis and treatment. The health questionnaire will be filled out and testing will occur at regular intervals. It is an international study which is expected to involve over 100,000 participants. You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this research.

There is minimal risk to obtaining blood drops for testing 25(OH)D. The test generally will be done in your home, using a sterile self-loaded lancet to puncture the fingertip. This will be done after a thorough washing of hands with soap and warm water and the use of an alcohol swab where the blood drops will be obtained. We are aware of no reports of harm other than short term pain with using the test. You are advised that if any complications develop you should consult your healthcare provider. You will be advised if there is any new information that would influence your decision about participation.

Your alternative to participating in this study includes requesting your own physician to order the 25(OH)D test. Results from physician ordered tests can only be used by participants of a qualifying GRH project and if the physician and lab are contracted with GRH. You can use the free educational pieces on the website without participating in the study. Contact Jen Aliano at (760) 710-9305 for questions about the research or if you think you have been harmed as a result of joining this research. Contact the Western Institutional Review Board (WIRB) if you have questions about your rights as a research subject: 1-800-562-4789. WIRB is a group of people who perform independent review of research.

Your individual health data will be kept confidential except for where required by law. The accumulated data will be stored in a secured, encrypted database operating behind a firewall, and password protected. The only person that will have access to the identified data will be our primary data biostatistician. This will be for purposes of accessing hospital records as indicated and released by participants. The de-identified health information is shared so the research can be conducted, properly monitored and published. The Principal Investigator and other
researchers will access the data in a de-identified form. For all analyses only an arbitrary number will identify the participant.

If you are under 18 years of age, parental consent must be provided to participate in this study. This permission will not end unless you cancel it. You may cancel it by sending written notice to the study leader at: GrassrootsHealth, 315 S Coast Hwy 101, Suite U-87, Encinitas, CA 92024.

Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating. There may be a sponsorship fee associated with participation in this study. Sponsorship supports the efforts of documenting serum levels and health outcomes, feedback of the information, as well as the tests and laboratory fees.

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