

Potential Participant Name: _____

PCOS Research Study- Principal Investigator: Dr. Anil Pinto

For Study Use Only:

Study ID# _____

PCOS Research Study Screening Questionnaire:

Please initial next to the statements that apply to you.

Inclusion Criteria:

- _____ Diagnosis of Polycystic Ovary Syndrome (PCOS) by a physician
- _____ Female age 21-40 years old
- _____ BMI 25-40 kg/m²
- _____ Willingness to comply with study protocol for 6 months + 3 month observational follow-up
- _____ Not actively planning pregnancy during study duration (approximately 10 months)
- _____ Willingness to give written informed consent for study participation
- _____ I currently have medical insurance (other than Medicaid)
- _____ I currently do not have medical insurance (or have Medicaid) and I would consider paying laboratory fees to be able to participate in the research study.

Other Health History:

Please initial next to any of the following statements that are applicable to your current health or personal health history:

- _____ I am currently on a prescription medication classified as an insulin sensitizer, anti-diabetic medication, oral contraceptive, anti-androgen, or lipid or cholesterol lowering medications. Do not initial if **Metformin** is the only applicable prescription you are on.
- _____ I am currently on oral birth control or other contraceptives.
- _____ I have a personal history or current diagnosis of one of the following conditions: Myocardial infarction (heart attack), angina, cardiovascular surgery, congestive heart failure, cardiac arrhythmias, conduction abnormalities, cerebrovascular accident, transient ischemic attack (TIA), peripheral vascular disease, deep vein thrombosis or pulmonary embolus.
- _____ I have been diagnosed with Diabetes Mellitus (Type 1 or Type 2)
- _____ I have been diagnosed with any autoimmune disease such as inflammatory bowel disease, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, polymyositis, scleroderma and/or thyroiditis.
- _____ I have a known infection with HIV (Human Immunodeficiency Virus), Tuberculosis or Hepatitis B or C.
- _____ I have significant liver or kidney disease such as cirrhosis or non-alcoholic fatty liver disease, glomerulonephritis, and/or undergoing dialysis treatment.
- _____ I have a history of cancer other than basal or squamous cell carcinoma of the skin.
- _____ I have a history of weight loss surgery.
- _____ I have a serious mental illness including depression, manic episodes, post-traumatic disorder, obsessive-compulsive disorder, personality disorders, history of attempted suicide or violence within the last 12 months.
- _____ I have smoked or used nicotine containing products within the last 30 days or would be unable to avoid using these products for the duration of the study (approximately 10 months).
- _____ I have used oral or injectable corticosteroids in the last 45 days.
- _____ I have used a multivitamin, fish oil, or product containing vitamin D and am unwilling to discontinue use for four weeks before beginning the study.
- _____ I have a history of significant cognitive impairment.
- _____ I am in or have been through clinical or surgical menopause.
- _____ I have a serious, unstable illnesses including cardiovascular, hepatic, renal, gastroenterological, respiratory, endocrine, neurologic, immunologic, or hematologic.
- _____ I have a gastrointestinal diagnosis or history known to interfere with absorption or excretion of food or drugs or a surgery that affects GI function including weight loss surgery.

Other Health History Continued:



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Please initial next to any of the following statements that are accurate based on your current health or personal health history:

- _____ I have not used drugs such as marijuana, cocaine, phencyclidine (PCP) or methamphetamines within the last 12 months.
- _____ I do not have a history of alcohol abuse or alcoholism within the last 12 months.
- _____ I speak and write English fluently.
- _____ I am not pregnant or breastfeeding at this time.
- _____ I am not currently planning a pregnancy within the next 10 months.
- _____ I do not have uncontrolled blood pressure.
- _____ I do not currently have hypothyroidism, hypoprolactinemia, congenital hyperplasia, androgen-secreting tumors, or Cushing's syndrome.
- _____ I am not currently enrolled in another clinical research study at this time with the exception of any observational studies.

I attest that I have answered the questions above to the best of my knowledge with accurate answers. I understand that by signing below that I give my physician permission to submit this form and the medical information contained within it to study coordinators and staff of Healthy Living Dallas and to be contacted by them for the purpose of research study enrollment.

Please initial the statements below:

- _____ I have read and reviewed the proposed study schedule of visits and am interested in pursuing participation at this time.
- _____ I understand that this study has three different groups of participants as outlined in the study informational pages.
- _____ I am currently interested in participating in Group 1 & 2 of the study which do involve lifestyle modifications and dietary counseling during the course of the study.
- _____ I am currently interested in participating in Group 3 of the study which do not involve lifestyle modifications during the course of the study.

Potential Participant Signature: _____

Printed Name: _____ Date: _____

I would like the staff of Healthy Living Dallas to contact me with more information regarding eligibility for this research study. Please write clearly and legibly.

Patient Full Name: _____ Date: _____

Patient Phone Number: _____ Phone Type: Cell / Home / Work

Patient Email: _____

Patient Address: _____

I agree to be contacted by the following methods: Phone Email

