Consent to Participate in a Research Study

TITLE OF STUDY: "Is Iron Status Related to Vitamin D Status?"
Iron Deficiency and Vitamin D Deficiency in Female State Fair Attendees

PRINCIPAL INVESTIGATOR: **Daniel D. Gallaher, Ph.D.** **dgallahe@umn.edu**
Department of Food Science and Nutrition
University of Minnesota - St. Paul campus
225 FScN
1334 Eckles Avenue, St. Paul, MN 55108
612-624-0746 (office) 651-233-8587 (cell)

CO-INVESTIGATORS: **Joannie Dobbs, Ph.D., C.N.S.** **dobbs@hawaii.edu**
Human Nutrition, Food, and Animal Sciences,
University of Hawaii at Manoa
1955 East-West Rd., Honolulu, HI 96822
808-956-3845 (office) 808-341-1530 (cell)

Sabrina Trudo, Ph.D., RD **trudo@umn.edu**
Address – Same as above for Dr. Gallaher
612-625-1785 (office)

INTRODUCTION:
Before you decide whether or not to participate in this study, it is important that you know the following:

- The purpose, procedures, benefits, risks, discomforts and precautions of the study
- You will be one of approximately 200 participants and must be a female between 18 to 45 years and not pregnant.
- Taking part in this study is of your own free will.
- You may decide not to take part in the study or stop being in the study at any time.
- If you agree to take part, you will be asked to digitally sign this consent form. If you sign this form you are agreeing to take part in this study and to allow the research team to use and disclose your health information. A copy of this consent signed by the principal investigator will be given to you to keep for your reference.

PURPOSE:
Nutrient deficiencies can impair health and decrease the quality of life. Iron deficiency is the most common nutrient deficiency, especially in women of reproductive age. Vitamin D deficiency is the fastest growing vitamin deficiency in America today. Because iron is necessary to activate vitamin D, the purpose of this study is to determine whether individuals who have a lower iron status, with or without anemia, may also have low vitamin D status. Both of these nutrients have some association with depression. This research will be used in the future to understand more about nutrient interaction and to decrease these deficiencies by developing evidence-based public health nutrition recommendations.

PROCEDURES:
This study consists of this survey that will be linked to your blood values. To keep your information confidential, you will be provided with a unique assigned number.

You will be asked to provide a 10 mL blood sample (about 2 teaspoons) that will be analyzed for iron status, vitamin D status and total cholesterol, a precursor of vitamin D.

Height and weight will be measured and percent body fat will be estimated from a bioelectric impedance type of floor scale. Your body mass index (BMI) will be calculated from height and weight. Ear temperature will be measured with a standard ear thermometer and blood pressure will be measured using a wrist monitor technique.

Additionally you will be asked to complete a lifestyle questionnaire about your current use of medications, dietary supplements, and usual food consumption and a set of questions related to potential symptoms of iron deficiency and vitamin D deficiency.

DURATION:
Your participation in this study will consist of one study visit to complete questionnaires and provide a blood sample for assessment of iron status. This complete process will require between 30 to 60 minutes of your time. The survey questions are mostly multiple choice questions with a few questions where you may add an open ended response. Completing the survey will take about 10 to 15 minutes. All data will be stored on a password-protected computer and password-protected flash drive.

COMMUNICATION OF YOUR RESULTS:
To receive the results of your blood tests, you must provide an email address where the blood values can be sent. The results will be sent to this address without personal identifying information and only with a participant number you will be given during your study visit. Please provide an email address at which you are the only person who reads the email messages.

Email address: _____
I verify that I am the only person who reads the messages at the above email address. _____ (please initial)

FORESEEABLE RISKS OR DISCOMFORTS:
There are few risks in participating in this study, however the study may involve the following risks and/or discomfort:

- Blood drawing can cause mild pain or a bruise at the place where the needle is inserted. Occasionally, a person may faint or feel faint when blood is drawn. The risk of infection is slight since only sterile, one-time equipment will be used.
- In the extremely unlikely event that your survey responses were accessed by an unauthorized individual, it is possible that you might be uncomfortable or embarrassed with that knowledge.
- There also may be risks and discomforts that are not yet known.

BENEFITS:
There may be no direct benefit to you for taking part in the study. You will receive the results of your height, weight, percent body fat, blood pressure, and ear temperature measurements during your visit. The blood test results will be sent to you via email as described below. These measurement values may provide you with helpful baseline information about your personal health status. If your blood pressure, ear temperature, or blood test results are out of the normal range,

you will be notified so that you may contact your private physician for follow up.

You may find that certain conditions you are experiencing may be linked to iron deficiency or vitamin D deficiency, and therefore are highly treatable by improving your iron or vitamin D status.

COMPENSATION:
You will receive payment of $10 in cash for completion of the survey and giving of your blood as compensation for your time.

FINANCIAL COSTS TO THE SUBJECT:
There are no anticipated costs to participants in this study; however, if you are injured or need medical treatment in the course of the study, you alone may be responsible for the costs of treatment.

CONFIDENTIALITY:
Every effort will be made to maintain the confidentiality of your information. Your information will be assigned a study number. This number and associated data will be stored separately from your name. The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality.

VOLUNTARY NATURE OF THE STUDY:
Participation in this study is voluntary. If you decide to participate, you are free to not answer any question or to withdraw at any time.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION:
In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality.

CONTACTS AND ANSWERING YOUR QUESTIONS:
The researchers conducting this study are: Daniel D. Gallaher, Joannie Dobbs, and Sabrina Trudo. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact Dr. Gallaher at 612-624-0746, dgallahe@umn.edu; Dr. Dobbs at 808-956-3845 dobbs@hawaii.edu; or Dr. Trudo at 612-625-1785 trudo@umn.edu.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455; (612) 625-1650

VOLUNTARY STATEMENT OF CONSENT:

To participate you must be a female nonpregnant woman between the ages of 18 years and 45 years without serious health issues. You must have read the above information, asked any questions

you have, and have received adequate answers. ***Completion of the survey implies your consent to participate in this research project.***

To Access the Survey: Check "I consent" on the question at the end of the informed consent form on the survey.

A SIGNED COPY OF THIS CONSENT FORM WILL BE GIVEN TO ME.

_____	_____
Research Participant's Name (Print)	Research Participant's Signature

Your Participant Code: _____

_____
Principal Investigator's Signature