Informed Consent Form

for Research Project:
"Is MyPlate.gov approach to helping overweight patients lose weight more patient-centered?"

clinicaltrials.gov # NCT02514889

conducted by William J. McCarthy, Ph.D., Lillian Gelberg, MD, MSHS, and Melvin Rico, BA
University of California, Los Angeles

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Informed Consent Form for the Healthy Weight Loss Study

"UCLA/TCC Healthy Weight Loss Study"
PCORI Grant # R-APD-1306-01150

We are asking you and about 270 other adult members of the Long Beach community to be part of a research study being conducted by investigators Dr. William McCarthy, Ph.D., of the UCLA Fielding School of Public Health and Dr. Lillian Gelberg, MD, MSPH, of the UCLA David Geffen School of Medicine and UCLA Fielding School of Public Health. Other investigators include Dr. Maria Chandler, MD, Ms. Evangelina Ramirez, and Ms. Stephanie Love, all associated with The Children's Clinic of Long Beach (TCC). We are conducting this study because we want to learn better ways to help TCC patients who want to lose unwanted body weight to do so safely and effectively by helping them to change their exercise habits, their daily food choices and their choices of leisure time activities.

Why is this study being done?
By taking part in this study, you will help us better understand some of the ways in which medical and public health professionals can help TCC patients and their families to achieve a healthy weight by improving their health-related lifestyle choices. **Your participation in this study is entirely voluntary**. You should read the information below and ask questions about anything you do not understand before deciding whether or not to take part in this study.

What will happen if I take part in this research study?
If you agree to take part in the study, you will be randomly assigned to one of two lifestyle coaching programs to lose unwanted body weight: a program that encourages eating more healthy foods that fill you up on fewer calories, like fresh fruit, vegetables, and whole grains or a program watching how many calories you eat, which is the program used in the Diabetes Prevention Trial. You will have a personal health coach to help guide you through the program. Each of these programs will involve 11 sessions with your personal health coach with one session a week during the first 3 months of the study. Seven of the sessions will be telephone coaching sessions that take about 20 minutes. Two additional sessions with the community health coach will be in your home and will occur at the beginning and towards the end of the program. These home visits will take about 50 minutes each. The remaining two sessions will be two group lifestyle coaching sessions at The Children's Clinic that will last up to 2 hours each. The purpose of the health coaching sessions is to discuss your progress in making the changes recommended in either of the weight loss conditions. At the very end of the study there will be a final congratulatory meeting where study participants will get a certificate of completion and will have the opportunity to find out more about all aspects of the study.

In addition to the lifestyle coaching sessions, you will be asked to participate in study assessments that will include questions about your food and physical activity habits at the start of the study and at 6 months and 12 months follow-ups. At each of these sessions, we will measure your blood pressure, pulse, weight, height, and waist size. At your 6-month and 12-month follow-ups, we will ask you to share with us your thoughts about participating in this study.

Review of medical records

In addition, we will ask you to sign a separate consent form (HIPAA Authorization form) that gives us permission to review your TCC medical records for information on your prior and current health conditions, medications you were taking during the 18 months before your enrollment in the study, and for 60 months after the study has ended or information to confirm acknowledgment in your medical record that you had enrolled in the TCC/UCLA Healthy Weight Loss program. Additional information on your health-related behaviors will be recorded from your medical records by one of the study researchers. This study will in no way affect your regular health care at The Children's Clinic of Long Beach.

Use of collected data

At the end of this consent form, you will be asked to indicate if you would permit the researchers to use the information that you provided us during the Healthy Weight Loss Study to be used for future research purposes and data analysis and if you agree to be contacted for possible involvement in future research studies.

How long will I be in the research study?
Participants will be active participating in the research study for 12 months. The lifestyle coaching will occur weekly during the first 3 months of the study. The first study assessment will take place when you start the study and then at 6 months and 12 months later. Participation in the study is expected to require 1 ½ hours for each assessment. The program will include 2 hours for each of two group education sessions, 50 minutes for each of two home visits, and 15-20 minutes for each of 7 telephone health coaching sessions with a community health worker. Total participation time for the research study is estimated at 12 1/2 hours over 12 months. After the 12 months follow-up assessment, all additional data gathering is expected to rely on data in the study participant's medical record for up to an additional 48 months of follow-up.

Are there any potential risks or discomforts that I can expect from this study?
Although you might feel anxious and/or distressed about answering some of the questions (for example: about weight) during the study, taking part in this study is not expected to result in any significant harm.

Are there any potential benefits if I participate?
Taking part in this study may provide you with practical information about ways to eat more healthfully, and exercise more.

Anticipated Benefits to Society
Your participation will help us identify which of two popular approaches to encouraging patients to lose excess body weight is most effective. If results show that one approach is clearly superior to the other, this information could then be used to improve the health of other TCC patients in your community and across the country.

Alternatives to Participation
You do not have to take part in this study. Whether or not you take part in the study **will not** affect your care at The Children's Clinic of Long Beach or your relationship with UCLA.

Will I receive any payment if I participate in this study?
You will be given a gym bag with exercise tools and informational materials (a combined value of $85) that include a lifestyle coaching booklet containing important information to improve your health. In addition, you will receive compensation for answering questions and providing weight and blood pressure information at each of the three assessments: $20 at the start of the study, $30 at 6-months and $50 at 1-year follow-up. You will also receive $10 to offset travel costs to each of two group education sessions that will be offered to you.

Will information about me and my participation be kept confidential?
The information that you give us is for research purposes only. No information about you, or provided by you during the study, will be disclosed to others without your written permission, except: if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or if required by law. We will not report results of this study with your name or report any information that identifies you.

Withdrawal of Participation by the Investigator
Researchers at UCLA may stop you from participating in this research if things happen that warrant their doing so. For instance, if the researchers see that you are not feeling well, either physically or emotionally, we may stop your participation.

What are my rights if I take part in this study?
Your participation in this research is VOLUNTARY. If you decide not to participate in this study, it will not affect your relationship with The Children's Clinic of Long Beach or your relationship with UCLA. If you decide to participate, you can refuse to answer any questions, and you can end your participation at any time without penalty. Ending your participation will not affect your future care at The Children's Clinic of Long Beach or anywhere else where you receive health care.

Who can answer questions I might have about this study?
If you have any questions, you can ask a member of the research team, or you may contact Dr. William McCarthy or one of his staff at UCLA, (310) 794-7587, or contact Dr. Gelberg or one of her staff at UCLA at (310) 794-6092.

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please contact the OHRPP (Office of the Human Research Protection Program) at (310) 825-7122, by email: mirb@research.ucla.edu or write to: UCLA OHRPP, 11000 Kinross Avenue, Suite 211, Box 951694, Los Angeles, CA 90095-1694.

INITIALS OF RESEARCH SUBJECT
I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM AND INITIALING THE BOXES BELOW, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

CONTACT FOR FUTURE STUDIES
Please check the appropriate box below and initial:
___ I agree to be contacted for future research studies
___ I do NOT agree to be contacted for future research studies

KEEP AND USE COLLECTED DATA DURING THIS STUDY FOR FUTURE STUDIES
Please check the appropriate box below and initial:
___ I agree for the collected data to be kept and used for future research studies
___ I do NOT agree for the collected data to be kept and used for future research studies

SIGNATURE OF RESEARCH PARTICIPANT

I have read (or someone has read to me) and understood the procedures described above. My questions have been answered to my satisfaction, and I agree to take part in this study. I have been given a copy of this form.

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT (INVESTIGATOR)
In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to take part in this research study.

_____
Name of Investigator

_____ _____
Signature of Investigator Date