Children's Hospital Los Angeles

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

W8Loss2Go: iPhone App for Weight Management

Subject's Name:			
CHLA#:		Birth Date:	

- **INTRODUCTION**

You are invited to participate in a research study conducted by Alaina Vidmar, MD andClaudia Borzutzky, MD from the EMPOWER Weight Management program at Children's Hospital Los Angeles (CHLA). This research is sponsored by E Health International (EHI), Inc. You are invited to participate in this study because you were referred to the CHLA EMPOWER clinic, and are between 12 and 18 years of age. Participation in this study is completely voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

- **PURPOSE OF THE STUDY**

The purpose of this study is to evaluate the effectiveness of an iPhone app intervention, W8Loss2Go, for weight management for pre-teens and teens. We want to learn more about how teens can lose weight and develop healthy eating habits by using this iPhone app.

- **PROCEDURES**

Participation in this research will last approximately 12 months. If you volunteer to participate in this study, we would ask you to do the following things:

Initial Visit

The following research procedures will happen after you have completed your first EMPOWER clinical visit (same day). We will ask your parent/ legal guardian to complete a questionnaire that contains 20 questions and should take approximately 7-9 minutes to complete. At this visit, we will provide you with the W8Loss2Go app and two wireless scales, one to weigh yourself and one to weigh food. We will weigh you and measure your height in a private area and then ask you to enter this information into the W8Loss2Go app.

This study requires an iPhone 4S or 5 because the W8Loss2Go app is not compatible with android phones**.** If you do not have an iPhone 4S or 5, we will loan you one for the duration of your participation in this study. If you will use your own iPhone 4S or 5, we will install the W8Loss2Go app on it. You will register with a code name of your choice and a password on the app and fill in the user information. A member of the study team will go through each section of the app with you.

[1] This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

The iPhones used in this study, no matter whether it was loaned or you are using your own phone, should be kept charged and on you at all times during the day (except at school, if applicable) so that messages and alerts are not missed from the study team. The iPhone will be the primary way of communication during your participation in this study.

During the next 6 months we will ask you to do the following:

- **Your Weight and Weight of Food:** You will need to weigh yourself and the food you eat at home daily using the wireless scales provided to you. The wireless scales will automatically enter the information in the W8Loss2Go app. If wireless scales are not used, you will need to enter the information into the app.
- **Identification and Withdrawal of Problem foods:** We will ask you to identify your problem foods (e.g. candy, junk food, etc.). After you have identified these foods, you will begin the process of withdrawing each problem food identified for a minimum of 10 days, one or two problem foods at a time. A variety of techniques (e.g. gross pictures, motivational tools, coping skills to avoid comfort eating and white noise) that are available in the W8Loss2Go app will be used. You will do this for 10-12 weeks.
- **Snacking Panel:** The Snacking Panel helps you to stop eating between meals. The Snacking Panel uses a small steps approach. You pick one or more time periods of day when you will avoid snacking -- morning, afternoon, evening, or nighttime. Once you've been able to avoid snacking during a time period for at least 10 days in a row, that period is designated "In-control," and you can then work on a second time period. Snacking elimination is the goal before starting amounts reduction at meals. You will do this for 4-5 weeks.
- **Amounts of food:** The amount of food you eat will be addressed with the goal of reducing the amount of non-problem foods you eat. This will be achieved by such techniques as cutting serving sizes, not having second helpings, using smaller plates, weighing/measuring foods, stress reduction, and relaxation techniques. Information on these techniques are available in the W8Loss2Go app. You will do this for 4-5 weeks.
- **Telephone Conversations:** A member of the research team will call you once a week to discuss any barriers you may be experiencing. These conversions will be audio-recorded for educational purposes and should last approximately 15 minutes. The audio recordings will be transcribed and personal identifying information will be removed. Your code name will be used during these conversations.
- **Other W8Loss2Go features:** You may be asked to use some of the other features on the W8Loss2Go app by a member of the research team.
- **Study Visit:** Come to CHLA 3 months into the study for a weight check and face to face meeting with the mentors. This visit will take approximately 30 minutes.

Follow-up Visit

At the end of 6 months, you will return to the clinic to have your weight and height measured and completion of a questionnaire by your parent/legal guardian. The iPhone will be returned to us if you borrowed one while participating in this research. This visit will last approximately 30 minutes. All participants will be offered return to the EMPOWER clinic for further follow-up upon completion of the study if desired

At 12 months, you will return to the clinic to have a final measurement of your weight and height. This visit will last approximately 15 minutes. At this time, your participation in this study will end.

Participant Responsibilities for Personal iPhones

Participation in this study requires an iPhone 4S or 5. The W8Loss2Go app is not compatible with android phones so participants using their own phone must agree to have the app installed. Participants that use their own phone will continue to be responsible for their iPhone and service plans.

Participant Responsibilities for Loaned iPhones

These phones have an AT&T service plan for the duration for the study. The service plan includes unlimited texting, 3 GB of data, unlimited voice calls to and from other cell telephones, 700 voice call minutes for calls to and from landlines and unlimited night and weekend calls to and from landlines. International calls or texts including Canada are NOT allowed and not covered. Participants and/or their parents/legal guardians will not be responsible for the service plan or lost/damaged phones. The iPhone should be returned at the end of study in good working order.

The iPhone and accessories (e.g. charger, plug, ear phones) should be protected against loss or damage by keeping the protective skin on the iPhone screen at all times and by not removing or replacing the protective case at any time. Alerts and notifications should not be disabled and nothing should be stored on iCloud during your participation in this study. The principal investigator should be contacted if the iPhone is unusable, damaged and/or lost during your participation in this study. The iPhone should not be taken to ATT or the Apple Store for any reason.

If the phone is not returned at the end of the study, the AT&T service will be immediately terminated by AT&T, and the iPhone will be listed as "stolen property" in AT&T's database and will be unusable.

- **POTENTIAL RISKS AND DISCOMFORTS**

The risk of any harm to participants from participation in this study is low. This research involves the potential risk of accidental release of confidential information. You may feel uncomfortable answering some the questions. You can choose to skip or stop answering questions at any time. To date the program has been successfully trialed in a group of 40 young people in the US and no adverse effects were observed.

- **ANTICIPATED BENEFITS TO SUBJECTS**

You may or not benefit from participation in this study. Potential benefits to you include: weight loss, development of healthy eating habits, including portion control, elimination of frequent snacking, and reduced portion sizes.

- **ALTERNATIVES TO PARTICIPATION**

As this is not a treatment study, the alternative to participation is to not participate. The standard of care for your condition to continue monthly follow up in the EMPOWER clinic and meeting with a multidisciplinary team to develop treatment strategies for sustained weight loss.

- **ANTICIPATED BENEFITS TO SOCIETY**

Your participation in this study may allow us to learn more about how pre-teens and teens can lose weight and develop healthy eating habits by using an iPhone app in the future.

- **PAYMENT FOR PARTICIPATION**

There are a total of 10 points you can earn while participating in this study. If you earn 6 or more points, you will receive $300. If you earn 3-5 points you will receive $200 and if you earn 0-2 points, you will receive $100. All payments will be given to you as a gift card at the the 6 month visit. If you desire you may keep the food and body scale after completion of the study for continued use. The following table shows you which research procedures must be completed to receive points.

Research Procedure	**Points**
Meet with the study team after your first EMPOWER clinical visit	1
Have your weight and height measured by the study team	1
Enter your weight daily into the app	1
Weight the foods you eat at home daily	1
Enter data daily into the app as requested by the study team	2
Respond to messages/voicemails from the study team within 24 hours	1
Participate in weekly phone calls with the study team	1
Complete the exist questionnaire, have your final weigh in, and return the loaned iPhones	1
Use the iPhone as your primary cell phone	1
Total	**10**

- **FINANCIAL OBLIGATION**

This research study is funded by EHI. Participants and their families are not responsible for any of the costs involved in this study. Neither you nor your insurance company will be billed for your participation in this research. However, participants that use their own iPhone will continue to be responsible for their iPhone and service plans.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

It is important that you promptly tell the study doctor if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person, or call him/her at 323-361-3385. If you are injured or become ill as a direct result of participating in this study, CHLA will provide necessary medical treatment. The costs of treatment may be billed to you or your insurer like other medical costs. CHLA has no program to provide you with any additional compensation as a result of any injuries. You do not waive any liability rights for personal injury by signing this form.

- **PRIVACY AND CONFIDENTIALITY**

The information that you enter into the app will be looked at by members of the research team and EHI regularly. This is done in order to monitor the proper use of the app and your weight loss. The information you enter into the app will be coded. This means that your identifying

information such as your name will not be used; rather, the code name you have chosen will be used.

Members of the research team and, if appropriate, your physicians and nurses will know that you are a research subject. All results will be kept confidential but may be made available to you and/or your physician, if you wish. No information about you or provided by you during the research 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 (i.e., child or elder abuse, harm to self or others, reports of certain infectious diseases).

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised. You have the right to review the tapes if you desire. The audio-tape recordings will be transcribed and any personal identifiers will be removed before the discussion is reviewed by the research team.

Authorized representatives of EHI and the CHLA Institutional Review Board (IRB) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. Your choice about whether or not to participate will have no effect on your care, services or benefits at Children's Hospital Los Angeles. If you agree to participate, but later decide to withdraw from this study, you may do so at any time without affecting your rights to health care, services or other benefits at Children's Hospital Los Angeles. Please contact the Principal Investigator if you wish to withdraw from the study.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if necessary to protect your health, if you are unable to continue in the study, or if other situations arise that make it necessary to do so. If you experience certain side effects or become ill during the research you may have to drop out even if you would like to continue. The investigator, Alaina Vidmar, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **NEW INFORMATION**

If there is significant new information found during the course of the study or the research plan is changed in a way that might affect your decision to continue participating in the study, you will be informed and your consent to continue participating in the study may be requested.

- **HOW TO OBTAIN INFORMATION**

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. Alaina Vidmar at 323-361-3385

Evenings, nights, weekends or holidays you may call the hospital number, 323/660-2450 and ask for the Endocrinology Service doctor on-call.

- **FINANCIAL INTEREST OF THE INVESTIGATOR**

Funding for this research study is provided by EHI. The amount of funding is not based upon the number of research subjects enrolled. If your physician is an investigator for this study he/she is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your physician.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please provide your initials beside your decision.

_____Yes _____No [for subject to complete, if the subject is 14 years or older]

_____Yes _____No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

_____

Print Name of Subject

_____ _____

Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

_____ _____

Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____

Signature of Parent/Legal Guardian Date

_____ _____

Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____

Print Name of Individual Obtaining Consent

_____ _____

Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

My signature as Witness indicates that the subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed this consent/permission/assent form in my presence.

_____

Print Name of Witness

_____ _____

Signature of Witness Date

SIGNATURE OF INTERPRETER (if applicable)

_____
Print Name of Interpreter

_____ _____
Signature of Interpreter Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

Please check appropriate box and sign below.

☐ The undersigned, _____, hereby certifies that verbal assent was obtained from the subject.

☐ Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information; etc.)

_____

_____

Date:_____

Time:_____ Signature_____

Routing of signed copies of the form:
1) Give to the subject if at least 14 years old (copy)
2) Give to the parent/legal guardian if subject is a minor (copy)
3) Place in the CHLA Medical Record (copy)
4) Place in the Principal Investigator's research file (original)