Children's Hospital Los Angeles
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Addendum to Consent Form for
Group Telehealth Weight Management Pilot Study

Subject's Name:	_____		
CHLA#	_____	Birth Date:	_____

You are currently enrolled in a research study at Children's Hospital Los Angeles. When you began the study you were under the age of 18 years and your parent or legal guardian gave their permission for you to participate. Now that you are an adult, you have the legal right to consent for your own continued participation.

The original consent form for the study is attached. A member of the research team will discuss the remaining study activities with you. Participation in this study is completely voluntary. Please read the information provided, and ask questions about anything you do not understand, before deciding whether or not to participate.

SIGNATURE OF RESEARCH SUBJECT

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 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 INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and have answered all of his/her questions. I believe that he/she understands all of the information described in this document and freely gives consent 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 voluntarily signed this consent 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

Routing of signed copies of the consent form:
1) Give to the subject (copy)
2) Place in the CHLA Medical Record (copy)
3) Place in the Principal Investigator's research file (original)

Children's Hospital Los Angeles

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

Group Telehealth Weight Management Pilot Study

Subject's Name:	_____		
CHLA#	_____	Birth Date:	_____

- **INTRODUCTION**

You are invited to participate in a research study conducted by Claudia Borzutzky, MD from the Diabetes and Obesity Program/Division of Adolescent Medicine at Children's Hospital Los Angeles (CHLA). This research is sponsored by the Obesity Treatment Foundation and supported in part by the University of California (USC) Clinical Translational Science Institute (CTSI) grant awarded to CHLA. You are invited to participate in this study because you are between the ages of 14-18 years old and you are either enrolled in or are eligible for the Empower weight management program.

Approximately 60 patients will be invited to participate. 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**

This study is being conducted by Claudia Borzutzky, MD and her research team, to explore the possibilities of providing weight management services to teenagers by using internet technology and cameras, in group sessions, while participants are in their own home. We want to explore this treatment method since we know that coming to our hospital, CHLA, can be difficult for many of our patients, since both they and their parents have to take off extra time from school and work to do so, in order to get here in traffic, park here, spend the afternoon with us in clinic, and then get home. We will compare the group that participates in this study ("Telehealth group") to similar patients who have already received our usual clinic care in the EMPOWER weight management clinic. Telehealth group participants will participate in twice-monthly online group sessions that will be led by a mix of the same types of providers that are in EMPOWER. Most often, a registered dietitian will lead the session.

- **PROCEDURES**

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

[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.

1. During your initial research visit to CHLA, we will collect your contact information, in particular your email address and/or cell phone number. We will also ask that you complete a questionnaire that asks about
    - your feelings about technology
    - your feelings about your life
    - your feelings about your weight and health
    - what you eat
    - your physical activity habits

The questionnaire should not take more than 20 or 30 minutes total to complete. If you have not had recent lab work with your personal physician including diabetes, cholesterol, and liver function testing in the last 6 months, we will schedule you to have "baseline" fasting bloodwork done in our Clinical Trials Unit lab. This will involve having a needle inserted in your vein in order to draw the needed blood samples. The total amount of blood drawn should be between one half and one tablespoon, which is equal to a minimum of about 6 mL and maximum of 15 mL.

2. As part of the Telehealth group,

    - You will be asked to participate in twice-monthly scheduled online group sessions with 5 or 6 other teens close to your age. The sessions will last approximately 60 minutes.
    - At each telehealth session, we will collect your medical information (including your weight, lab results, medications, and major life changes), as well as your current zip code and date of clinic visit onto a data collection form. We will collect general information about how the group session went as well. We will also make sure that the contact info we have for you is current.
    - All telehealth sessions will be recorded. The recordings may include audio of you, video of you (only if you have your camera turned on during the session), and video of the research staff running the session. You will be reminded that we will be recording before each session.
    - One of our research team members will also contact you by cell phone or email (whichever you prefer) twice a month, in between group sessions, and for brief coaching, lasting 5-10 minutes or less, each time. Coaching will involve the coordinator checking with you about how you are doing on your goals, and help guide you if you are having challenges or difficulties. The coaching session will be documented onto a data collection form.
    - Your parents will be given information about your participation in the sessions. They will be informed if you attended and what the topic of discussion was. They will not be informed of what you shared during the sessions. They will also receive a reminder about the upcoming session to help remind you to log on.
    - You will be asked to come in to CHLA twice more during the study – once at the 3 month point, and once at the end of the 6 month study period. During those two visits, you will be weighed and measured and have your blood pressure checked, and these measurements will be documented onto the data collection forms as well. At the 6 month visit, you will have blood tests done to re-check your diabetes, cholesterol, and liver function testing that were done before the study

sessions began. This will again involve having a needle inserted in your vein in order to draw the needed blood samples. The total amount of blood drawn should again be between one half and one tablespoon, equal to a minimum of about 6 mL and maximum of 15 mL.

- At those two visits, you will be asked to complete parts of the same questionnaire from the first day again.
- At the end of the 6 month study, you will also be asked to complete a survey about your satisfaction with your treatment, and you will be given the option to continue your care in the Empower clinic for weight management, if the clinic is still operating as it is currently.

- **RESULTS OF RESEARCH TESTS**

The results of the following research tests will be shared with you and your doctor, if desired (put in your medical records): Cholesterol test, hemoglobin A1C and glucose (diabetes) tests, and ALT and AST liver tests.

POTENTIAL RISKS AND DISCOMFORTS

There is the potential of accidental release of confidential information. This is especially true in this study, since the Telehealth group will involve use of an online meeting platform. Though we will do everything possible to choose a secure and confidential platform, we cannot guarantee 100% that non-participants will not be able to access the platform during sessions. Additionally, since the Telehealth group involves group sessions, by consenting to be in the study, you are consenting to the possibility of sharing some of your personal information and feelings with other group participants; this can sometimes be uncomfortable or stressful.

There is also a risk of pain, bleeding, and bruising associated with having your blood drawn. Additionally, there is the risk that some of the questions in the questionnaires that you will be filling out at the first, 3 month, and 6 month visits will make you feel uncomfortable. It is important for you to know that you may skip questions that make you feel uncomfortable. There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

- **ANTICIPATED BENEFITS TO SUBJECTS**

The potential benefits of the study include:

- Improvement in your weight and medical problems related to your weight, though it is possible that the telehealth approach will not work as well as our usual/previous treatment approach (EMPOWER clinic).
- The amount of time of that your treatment visits take may be reduced, if you are in the Telehealth group, since most of your “appointments” will take place online while you are at home.

Based on experience with this type of intervention program, researchers believe it may be of benefit to teenagers like you. Of course, because all young people respond differently, no one can know in advance if it will be helpful in your particular case.

- **ANTICIPATED BENEFITS TO SOCIETY**

Benefits to society from this study include evaluation of a potentially more "user-friendly" way of treating overweight and obesity, that is less disruptive to school and work, and potentially less expensive.

- **ALTERNATIVES TO PARTICIPATION**

The alternative to participating in this research study is to receive the standard of care for your condition. The standard of care treatments available for your condition are participation in our typical Empower weight management clinic, if it continues to operate as it has, with monthly visits with our multi-disciplinary team for 6 months or greater, or with your primary care and other specialty care physicians, if EMPOWER should reduce/eliminate its offered services.

You may also qualify for other clinical treatment research studies.

Please ask questions about all of your treatment options before deciding whether or not to participate in this research.

- **PAYMENT FOR PARTICIPATION**

You will be given a $10 Amazon gift card after completion of the 3 month questionnaires and a $20 Amazon gift card after completion of the 6 month questionnaires and lab work. This will be given directly to you (the teen participant).

- **FINANCIAL OBLIGATION**

This research study is funded by the Obesity Treatment Foundation and supported in part by the USC CTSI grant awarded to CHLA. Participants and their families are not responsible for the costs involved in the study itself or the blood tests they will have at their 6 month visit. Neither you nor your insurance company will be billed for your participation in this research.

Your family is responsible, however, for costs which may result from your participation in the study, such as time off of work, car fare, parking, baby sitter fees, food purchased while at the hospital, etc.

- **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 323-361-2153. 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 will 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**

Any information that we collect about you will be kept in a password protected computer file, and will be "coded" so that your identity is not associated with the information; the "code" sheet will be kept in a separate, password protected file.

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.

The video recordings made of you during this research will not be shared outside of the research team. They will be destroyed by the end of the research.

Authorized representatives of the USC CTSI, the Department of Health and Human Services, 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.

Because this study involves the treatment of a medical condition, a copy of this form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about what medications or procedures you are receiving in the study and treat you appropriately.

- **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

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 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, Claudia Borzutzky, 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. Claudia Borzutzky at 323-361-2153.

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

- **FINANCIAL INTEREST OF THE INVESTIGATOR**

Funding for this research study is provided by the Obesity Treatment Foundation and supported in part by the USC CTSI. 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)