Cover Sheet

Title: Early Prototyping and Usability Testing (ACPS)
NCT05719064
Date: 12/23/2024

Page 2 (Protocol and Data Analysis Plan))
Page 21 (Informed Consent Document)

Social Behavioral Protocol-Phase I

Study Title: Adaptive Cell Phone Support to Promote Medication Adherence among Adolescents and Young Adults with Chronic Health Conditions

PI Name: Caitlin Sayegh

Study Procedures

1. Background/Rationale

The transition to adult care is a vulnerable developmental period for adolescents and young adults (AYA) with chronic health or neurodevelopmental conditions (AYA; Blum et al., 1993). Achieving self-management skills is important for transition readiness (Betz et al., 2014). Unfortunately, medication adherence is a self-management skill many AYA find challenging, with rates of nonadherence commonly above 50% (Rapoff, 2010). Nonadherence can lead to worsened symptoms, poor quality of life, and, for some conditions, higher risk of mortality (Christensen & Johnson, 2002). Considering the high rates of cell phone use among AYA (Lenhart, 2015), delivering adherence interventions through mHealth technology could improve access to support. Scalability, the potential for an intervention to be implemented with large numbers of patients, is one major advantage of mHealth approaches. When assessing scalability, experts consider not only the effectiveness of an intervention, but also factors like patient acceptability and the required workforce (Milat et al., 2013). Cell Phone Support (CPS) is an mHealth intervention delivered by a human coach with signals of efficacy for promoting adherence among AYA with HIV, organ transplants, sickle cell disease, and type 2 diabetes (Belzer et al., 2014; Sayegh et al., 2018; Sayegh, MacDonell, et al., 2022). CPS involves frequent, brief (~5 minute) contacts from a human coach to keep AYA accountable for taking their medication, support them in problem-solving adherence barriers, and link them with resources. Unlike the majority of mHealth interventions, CPS focuses on a behavior (oral medication adherence) rather than a specific health condition, increasing its potential for reaching AYA on a large scale. Still, to optimize CPS for scalability, we need to make two improvements: 1) raise the acceptability of CPS to increase AYA willingness to engage in the intervention; and 2) reduce the intensity of human delivery to decrease workforce requirements.

2. Purpose/Objectives/Aims/Research Questions

Specific Aim 1: **Co-create Adaptive CPS, with computer- and human-delivered components (PHASE I—Funded by Barbara Korsch Ward Foundation, Marvin Belzer Merit Account, and USC Undergraduate Research Associates Program).**

- Aim 1A: Re-design CPS using human-centered design (HCD) principles with a youth advisory board to deliver foundational intervention components by computer, with human coaching available in response to patients' needs.
- Aim 1B: Conduct iterative, mixed-methods usability testing research to refine early Adaptive CPS prototypes by applying HCD evaluation methods (i.e., A/B testing).

Note. This aim is registered on ClinicalTrials.gov NCT05719064.

3. Participants (sample)

Patient Participants (Phase I)
Inclusion criteria for this study include: 1) Children's Hospital Los Angeles patient, 2) between 15-20 years old, 3) taking at least one oral medication per day for any condition, 4) English speaking, 5) access to a cell phone, and 6) demonstrating sufficient cognitive capacity to engage in the assent/consent process and study procedures. The intervention will be designed for mid-adolescents, late-adolescents, and young adults because these phases of development are when many youth are given greater responsibility for taking their own medications, and they are at higher risk of poor medication adherence related to their age. The intervention will be designed and delivered in English at this point due to limitations on resources and the expected linguistic competencies of most CHLA patients.

This study aims to recruit adolescents and young adults between the ages of 15-20. Minor children are included in this age range because mid-to-late adolescence is a key period for developing self-management and transition readiness to prepare for the transfer to adult health care systems. Caregivers and providers often begin allocating more responsibility to adolescents for taking their own medications at this age, and many youth begin to display nonadherence that puts their health or well-being at risk. Therefore, interventions are needed to promote the acquisition of transition readiness skills like medication adherence among adolescents. Both the PI (Sayegh) and primary mentor (West) are licensed clinical child and adolescent psychologists with clinical expertise delivering psychosocial interventions to youth.

We plan to allow participants from Phase I to join a subject/participant pool in terms of being reinvited to participate in a future phase of the study that involves testing the phone program again, if they still meet the eligibility criteria. We would not be using any other subject/participant pool. Phase I participants were asked whether they gave permission to be contacted for a future phase of research in the Phase I consent form.

The inclusion criteria explained above will apply for any Patient Participants in Phase I.

Patient Participants
We will use a broad recruitment strategy where there is "no wrong door" to enter to learn about and be screened for participation in the study.

- One way we will seek participants is through direct invitations from healthcare providers. We will educate our colleagues on the study through emails, physical and electronic flyers, and presentations made in clinical huddles, team meetings, or practitioner journal clubs, etc. The flyer will include a perforated section where providers can affix a sticker from the day's visit to automatically list the patient's name and contact information. Providers will provide information about the study to prospective patient participants (and if minors, their parents/legal guardians) and if they agree to have their contact information shared, the providers will send contact information to the study team via phone call, email, or interoffice mail.

- We will also add QR codes to flyers, train administrative assistants/clinic staff checking in patients to flag those eligible for the study and embed undergraduate research assistants/study staff in clinics several hours a week to assist with in-person recruitment and keeping the study front of mind. Language from consent forms may be used during in-person patient recruitment. We will frequently check in with providers to explore how we could improve the recruitment process and make amendments as needed.
- To follow the "no wrong door" model, we will not limit recruitment to provider invitations in the proposed research. We plan to use a wide range of approaches to match the needs and preferences of diverse youth throughout the hospital. Specifically, we will post physical flyers in waiting rooms, announce the study opportunity at Center for Healthy Adolescent Transition workshops and online newsletter, and post on the Children's Hospital Los Angeles Division of Adolescent and Young Adult Medicine Instagram account and on the https://www.chla.org/research/chla-clinical-research-studies webpage (with information to be in uploaded found in section 24.2). All recruitment materials will be generated with the youth advisory board.
- We will also do in person recruitment by staffing a table in the hospital lobby or other hospital sponsored events with study flyers and option to sign up to learn more (with permission from CHLA events team). At the tabling, we will have a CHLA laptop with us and participants can open a REDCap survey to type the interested participant's name, phone number, and email address. If the prospective participant is under 18, they will also be asked to type in their name, number, and email address of a parent/guardian. This ensures they do not see other prospective participants' information and that the contact information is collected in secure, HIPAA protected database.
- If subspecialty clinics are interested in allowing researchers to review their scheduled patients for particular clinic days, and identify those in the age range to be eligible for the study, and directly invite in person before or after their clinic visits, we will make a plan with each clinic willing to do so. We will include this option in the recruitment email sent to clinicians. If a clinician expresses interest in partnering with us in this way, we will invite them to a phone call or videochat to discuss the best method for their clinic to not interrupt clinic flow. We will ask them to share the Patient List in KIDS they are working from so that our research team can review scheduled patients each week, and then arrange with clinics to come in person and invite prospective participants to learn more about the study and express interest if they would like to participate. We will ask any clinician interested in partnering in this way to identify a contact person in their clinic we can communicate with to plan in person recruiting. If a participant in clinic is interested, the researcher will type the name, MRN, and preferred contact information (e.g., phone number, email address), and parent/guardian name and phone number for patients under 18 years old, directly into the excel screening log for this study, on a CHLA laptop. We will use an in person recruitment script. If there is an appropriate private space and time considering the prospective participant's schedule and the clinic's operations, we will offer to do written consent in person at the clinic. If not feasible or if prospective participant prefers to wait and consider more, we will schedule a remote conference for electronic consent.
- Providers, parents/legal guardians, and youth will be able to indicate interest via phone, email, clicking a link or following a QR code to a REDCAP survey, or in-person communication with research assistants/study staff in clinics. The REDCap survey will

be completed by those interested in learning more about the study and provide the study team with their contact information and preferred method of contact. Study personnel will check the REDCap each week to see if anyone has expressed interest and will contact the individuals directly based on the information they provide, to further explain the study. Then, study personnel will contact the prospective participant (and parent/legal guardian if youth is younger than 18 years old) by telephone or email based on their preference. If they select email, the PI will contact them by email to briefly describe the study and answer any questions by email. If the participant is interested in learning more after a brief email exchange, the study personnel will schedule a phone call.

- Regardless of the manner of referral (provider referral or self-referral), if the potential participant is interested in joining the study, the research personnel will schedule either a remote based or in-person conversation to give a more detailed explanation of the study and given the opportunity to ask questions. The study personnel will explain the study and answer any questions either the potential participant and/or their parent/legal guardian may have. The study personnel will also ask several screening questions (e.g., if between 15-20 years old, whether they take daily oral medication, etc.). If participants are eligible based on the screening questions, then study personnel will proceed with obtaining consent/permission/assent or schedule a longer conversation for later if preferred. As privacy is a top priority, all questions will be asked in a private setting, either privately over the phone/virtual platform (CHLA approved, HIPPA complaint platform) or in a private room.
- Screening data will not be placed in medical records. The screening data will be retained anonymously, and not linked via a code with identifiable information. Screening data is being retained so that we can highlight the differences between those that agree, those that decline to participate, and those that are not eligible to participate which could assist with the development of future studies.
- After the screening questions are administered, we will invite prospective participants who met all the screening criteria to enroll in the research study. If they decline enrollment in the full study, we will ask for verbal consent/permission/assent to participate in an abbreviated version of the study. This abbreviated version of the study involves administering a brief survey of demographic data, perceived acceptability of the intervention under study, and their reasons for deciding not to participate in the full study and is being done to inform future research studies.
- Potential participants that are found to be ineligible or that decide that they don't want to participate will be asked if we can keep their responses to the screening questions. Their responses will be destroyed if they say no.

Methods

Youth Advisory Board (YAB)

Before recruiting any research participants for participation in this study, we will form a youth advisory board (YAB) to guide this study. The PI previously conducted a study on Cell Phone Support (CHLA-20-00168) guided by a community/youth advisory board. This board helped identify the research objectives of the current study (Adaptive Cell Phone Support) and 6 of these YAB members would like to continue. As a team, we decided we would like to recruit 4

additional members, specifically hoping for representation from a few younger members, male-identified members, and ethnically and racially diverse members. The board members are young adults between the ages of 18-23 years old that take daily oral medications. They may be current or past CHLA patients. We plan to send an email with a YAB recruitment flyer to providers in subspecialty clinics at the hospital to identify new members of the YAB. Providers will provide us the contact information for nominees or nominees can contact us directly via our contact information in the flyer or QR code. Providers will be asked only to share contact information for prospective YAB members to the research team if they have given permission to their providers to share their contact information. YAB members are not research participants themselves—they are community advisors guiding the research.

The YAB will meet approximately every other month for up to 8 years, starting in the Summer or Fall of 2023. The meetings will take place virtually using CHLA-approved videoconferencing platforms. Board members will be compensated with a $40 gift card at each meeting. Members can choose whether to attend any scheduled meeting because there are no attendance requirements. Members can also step down at any time if they wish. Board members will be introduced to research skills, can include the service on their resume, and can obtain letters of recommendation related to their contribution to the board for job or college applications. If YAB members no longer wish to remain on the board, we will recruit new members.

After finalizing the YAB, we will re-review all proposed methods and procedures collaboratively and the PI will submit any necessary amendments prior to implementing anything.

This study will consist of four phases aimed at producing a highly scalable mHealth invention: 1) community-engaged development of and usability testing of early intervention prototypes, using HCD methods; 2) more extensive usability testing to ensure final version of intervention is ready for pilot trial, 3) a pilot SMART study to assess the feasibility, usability, acceptability, and preliminary efficacy of Adaptive CPS, and 4) an implementation planning study.

Phase I. Applying HCD Methods to Develop Highly Acceptable Adaptive CPS Intervention

Phase 1 has two aims: A) restructure CPS using HCD principles to deliver foundational intervention components by computer, with human coaching available in response to patients' needs; B) conduct iterative, mixed-methods usability testing to refine early prototypes of Adaptive CPS intervention.

Intervention Co-Design Process. We will follow several participatory HCD phases during YAB sessions (Harte et al., 2017). First, we will create a case document detailing the context of the use of Adaptive CPS, culminating in a basic prototype built on Computerized Intervention Authoring System (CIAS). We will follow a semi-structured agenda, using "make" questions (e.g., prompting YAB members to draw or create visual representations of their intervention ideas), "tell" questions (e.g., asking members to verbally express narratives and preferences relevant to the intervention), and "enact" questions (e.g., supporting members in trying Adaptive CPS via the CIAS platform in ways that resemble real-life use) (Vandekerckhove et al., 2020). We will iteratively improve Adaptive CPS until the researchers and YAB reach consensus that the intervention is ready for usability testing. Then, we will subject Adaptive CPS to rigorous usability testing by patients, stakeholders, and technology experts. We will take an iterative

approach: gaining feedback, discussing in the YAB, refining the intervention, and seeking more feedback throughout the design process.

Description of Adaptive CPS Intervention. Adaptive CPS will deliver as many of the original CPS components as possible via CIAS (e.g., checking in on recent medication adherence to increase accountability, facilitating identification of barriers and engaging in problem-solving, and linkage to resources; see Figure 2A for illustration of the difference between CIAS delivered CPS and human-delivered CPS components), and then offer human coaching consistent with participants' preferences for frequency (e.g., twice a week, daily) and modality (e.g., call, text) when needed (Figure 2B). CIAS will guide participants to check in about their current adherence; identify past, current, or future adherence barriers; brainstorm solutions; set an intention to try a strategy; and access resources or reach out to their medical team for help. For example, on Tuesday a participant might indicate they took their medication but expect a barrier tomorrow when they have band practice. They will be prompted to generate a list of possible solutions on their own or select from a library of commonly used strategies (e.g., setting an alarm; asking for an accommodation; storing a back-up dose). They will be prompted to select a strategy to try tomorrow and then on Wednesday, CIAS will populate the check-in with their selected solution (e.g., Hi, [participant]! Did you take your medication today? How did your plan for [asking for an accommodation] work?). Adaptive CPS will include a module for accessing human coaching that can be made available based on decision rules (e.g., insufficient treatment response by a given time). Subjects can provide additional information to the coach via a text box before the coach reaches out to them (e.g., I keep feeling nauseous. My doctor said that's normal but it's really bugging me, etc.). The coach will implement CPS as in the original model (Belzer et al., 2014; Sayegh et al., 2018, 2022) in addition to encouraging participants to continue using the CIAS components. The coaches will not provide treatment advice (e.g., discontinuation of medication(s), taking/starting new medication(s), etc.).

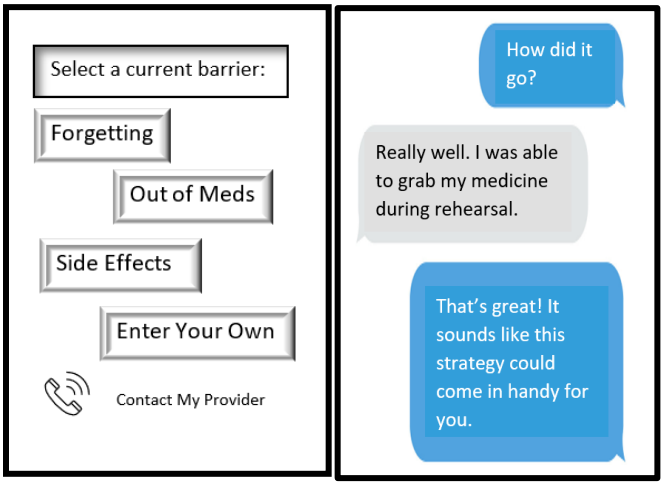

Figure 2A. CIAS prototype. Figure 2B. Human prototype.

See table on following page for prototype adjustments after each usability cohort.

Phase I Prototype Details Log

	Enrollment Initiated Date	Cohort Size	Adjustments
Prototype 1	1/26/2024	*n* = 6 (complete)	N/A. Original 4 sample screen shots in Section 40. These are no longer in use as of AM009.
Prototype 2	10/3/2024	*n* = 6 (complete)	Added coaching orientation video: Human Coaching Orientation: A video to explain what coaching entails was created with alumni from the Sayegh Laboratory. These alumni served as

			coaches on our earlier studies of the cell phone support intervention, and all have signed the CHLA media releases to allow their videos to be used. The video will be delivered to participants via the CIAS platform when they are offered the opportunity to communicate with a coach. Video uploaded in Section 40 and labeled "Prototype 2 Additional Video(0.01)".
Prototype 3	1/6/2025	*n* = 10 (complete)	Removed references to word "app" in participant-facing material. This is confusing to participants as they expect it to be an installed app on their phone, not texts + webpage + coaching. We will use the term phone program instead. We added an orientation module (see "Introductory Explanation for Program" in the IRB application) in CIAS to address some participants' confusion about what to expect in the information and how it was intended to work. • We added this language: "Welcome to CHLA Cell Phone Support! Over the next three weeks, you'll receive text messages with links to check in on your medication habits, identify any challenges, and brainstorm solutions. Coaches are also available by phone, text, or email if you need extra support. A coach will reach out to introduce themselves, but it's up to you whether you'd like to speak with them. We hope this program helps you stay on track with your medications." • We added an image of a puzzle to illustrate the problem-solving focus. We added a few new barriers and solutions based on common barriers and solutions discovered in user testing and recommended by youth advisory council. • We added a new solution to "taking medication makes me feel upset" barrier: Spiritual and religious coaching. Some people find spiritual or religion helpful to

			come to acceptance with their condition. Check out this website for lots of spiritual practices you can try: https://www.spiritualityandpractice.com/practices/features/view/27713/spritual-practice-toolkit • We added a new barrier "Hard to find privacy" and three solutions: 1) brainstorm a private spot, 2) start the journey to being open about taking medication , and 3) therapy • We added a new barrier "Left medicine at home" and three solutions: 1) Keep a Back Up Dose on me, 2) Keep a Back Up Dose at places Where I Spend Time, and 3) Ask my Health Care Team for Advice. • We added a new barrier "No one reminded me" and three solutions: 1) Learn to Take the Lead in my Own Health Care through resources on GotTransition.org, 2) Remember On my Own, But With a Back-up! and 3) Store my medicine somewhere I can see it, like on a dresser or close to your bed so it's easier to remember. • We added a new barrier "I'm trying to meet basic needs (e.g., housing, food)" and three solutions: Explore Youth-Specific Resources: Download the "What I Need App" to find youth-friendly resources or explore its website: https://oclawin.org/find-help/win-app-online/, 2) Ask My Health Care Team for Advice: Ask to speak with a CHLA social worker through your healthcare team, and 3) Find General Los Angeles Resources: Look up resources on the website https://211la.org/ or dial 211 to speak with someone We revised the coaching script to have a new first contact script, a mid-intervention contact script, and an end of intervention contact script based on user feedback and youth advisory board recommendations. See Section 40.

			Revised CIAS check-in for usability • Removed narrator so intervention can be used more quietly and because it was blocking some of the text on screen at times. • Removed requirement for them to input their own ID number. We will generate the invitation to them personally and title the instance of the intervention with their ID number to reduce user burden but maintain data clarity. We will provide them with their personalized link they can click from their phone through videoconference chat during the Phase I usability testing study during their Think Aloud activity, or via text message or email in the Phase 2 SMART pilot study based on their preferred method of receipt. The language of the invitation will be: "Thank you for signing up for the CHLA Cell Phone Support program! Please click this personalized link (made specifically for you) to start the program). {INSERT LINK}" • Rephrased check-in question for clarity (e.g., "Have you taken all of your prescribed medication over the past 24 hours?" instead of "today") • Added more instruction to the barrier checklist page: "There may be many reasons why it's hard to take your medication-- let's focus on one of the biggest barriers you are facing. Which barrier was the biggest challenge recently?" Maintain Prototype 2 "Additional Video" in Prototype 3 which explains what coaches do.

Phase I Patient Participant Research Procedures. We will use iterative convergent mixed methods following HCD principles to develop a highly acceptable intervention (Alwashmi et al., 2019). We will cycle through three rounds of Adaptive CPS three-week patient trial periods, with two scheduled in-person or video-conferencing user testing session following a think-aloud protocol for each patient participant (Ericsson & Simon, 1993). Participants will use the phone support tool onto their cell phone and will access the tool between 3-5 times per week to check in

about their medication taking, identify barriers, and solutions to taking their medications more consistently. No participants will have to install or download an app. The intervention will be delivered via opening a webpage on the internet browser. They will also learn about resources that could help them with medication adherence. The application will also include access to a human coach that can communicate with them with messages, texts, and/or phone calls. The think-aloud protocol involves having an interview with each patient participant. The first interview will take place before the 3-week trial period and will involve introducing the program to the participant and learning about their initial thoughts. Another interview will happen after the 3-week trial period and involves obtaining feedback from the participant. Each interview will last approximately 1 hour but could be longer depending on the discussion. The second interview will include a discussion prompt asking participants to choose which of several pictures reminds them of the intervention most, and how so. For the fourth cohort, we will add questions to the 2nd interview to ask them which of several options they think is the best name for the intervention. The interviews will be audio-recorded. We will also administer quantitative surveys via REDCap, taking approximately 15 minutes, after each of the two interviews. The study personnel will open the REDCap surveys on a CHLA laptop and provide this to the participant if meeting in person, or send the link through the teleconferencing chat function if meeting virtually. CIAS will record user engagement data throughout the three-week trial period (see CIAS User Data Export Plan in iStar). After running a first round of participants (n = 6) through usability testing, we will share de-identified summaries of results (i.e., no way of linking the data back to the subjects) with the YAB and adjust the intervention in response to feedback. Then, we will do the same with a second (n = 6), and third (n = 10)round of new participants. These cohorts represent a form of A/B testing through which we can evaluate how iterative improvements impact feasibility, usability, and acceptability metrics. The length of participation is 3 weeks. Participants from Phase I or Phase II will be given the option to participate in Phase III or Phase IV if they continue to meet eligibility criteria at that time, via an optional procedure subsection in the consent form.

The following self-report measures will be used: Patient Participant Demographics, mHealth App Usability Questionnaires, Theoretical Framework of Acceptability Questionnaire with an additional request for a rating between 1 and 5 stars, and Visual Analogue Scale. The Think Aloud Protocol with Qualitative Questions will be administered as an interview.

We will abstract information from Phase 1 participants' electronic health records (EHR) from the year prior to enrollment. Two research personnel will independently enter variables detailed in the Retrospective Chart Review guide (13.2) into a REDCap survey from the EHR. The purpose is to pilot the feasibility of the Medication Regimen Complexity Index tool before beginning Phase III.

Patients that decline participation in the full study during Phases I, II, and III:

Patients that are eligible for participation but that decline to participate in the full study, will be invited to participate in an abbreviated portion of the study. The abbreviated portion of the study will involve completing a demographic survey, a 14-item measure assessing perceived acceptability of the intervention, and providing the reasons as to why they declined participation in the full study if they consent/assent to this. The patients will be provided a link to the REDCap surveys by email or text message (based on their preference) if discussing the study on

the phone, or by being given a laptop with the survey open if discussing the study in person. The measures will take 10 minutes. We will not collect information from these patients' medical records or will any data from this study be placed in their medical records.

a. Instrumentation

i. **Phase I Measures**. Primary outcomes are feasibility, usability, and acceptability. Feasibility is defined as the extent to which a new treatment can be successfully used or carried out within a given setting (Proctor et al., 2011). Feasibility will be assessed quantitatively. Our first measure of feasibility will be defined by enrollment rates. In our pilot studies, we achieved enrollment rates of 53%(Sayegh et al., 2018) and 62% (C. S. Sayegh, MacDonell, et al., 2022). Our aim is to surpass 80% by using HCD methods to reformat CPS as an adaptive intervention. We will also assess feasibility by extracting engagement data recorded by CIAS such as the frequency and duration of times participants access Adaptive CPS, and the length of responses participants enter in open-text components of Adaptive CPS. We expect these values to increase with each usability cohort. Usability is defined as the ease with which users can use technology to achieve a particular goal (International Organization for Standardization, 1998). We will collect qualitative usability data using a think-aloud protocol and by asking participants to discuss the intervention's understandability, learnability, operability, and attractiveness. Usability will also be assessed quantitatively using the mHealth App Usability Questionnaire (MAUQ) ease of use and usefulness subscales (Zhou et al., 2019). In my prior pilot study of non-adaptive CPS, average scores were approximately 5.5 on these six-point scales (C. S. Sayegh, MacDonell, et al., 2022). Our goal is to surpass those scores, nearing the six-point level. (Khowaja & Al-Thani, 2020).Acceptability reflects the "extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention" (p. 4) (Sekhon et al., 2018). We will measure this construct quantitatively with the Theoretical Framework of Acceptability Questionnaire (Sekhon et al., 2022) with the addition of a face-valid item requesting a rating between 1 and 5 stars. Participants will rate the acceptability of Adaptive CPS before, during, and after the intervention. We will also ask eligible participants who decline to participate in the usability trial to give consent/assent to complete the acceptability measure, so we can understand how the intervention is perceived even by those who do not wish to try it. All qualitative usability and acceptability data will be collected via a think-aloud protocol, prompting patients to try different functions of the intervention and share their unfiltered thoughts, decision processes, and reactions, followed by a brief semi-structured interview. We will also pilot our chart abstraction tools to quantify the complexity of medication regimen (Medication Regimen Complexity Index; George et al., 2004), reporting these as participant characteristics in this phase. Finally, we will assess medication

adherence using the Visual Analogue Scale (Walsh et al., 1998) before and after trying the intervention for three weeks.

b. Data Analysis

i. **Phase I Analysis**. After each usability cycle, we will analyze the qualitative data using the rapid assessment process (Beebe, 2001). This approach is appropriate for time-limited research projects with specific research questions (Vindrola-Padros & Johnson, 2020) particularly when designing new interventions (Koenig et al., 2016). Rapid assessment involves transforming interview data into structured matrices facilitating the development of actionable results. Rapid assessment is an excellent fit for this study because we do not aim to generate theory, but rather obtain targeted feedback to inform iterative intervention development. For quantitative data, we will inspect summary statistics for feasibility, usability, and acceptability. After every cycle, we will examine item-level responses and total scores to process user feedback and inform iterative intervention improvements. In the final cycle, we will evaluate whether our enrollment rate surpassed 80% and whether MAUQ usability scores are higher than in our pilot work. The Wilcox sign rank statistic will be applied to test the null hypothesis ($Total\ Score = \mu_0$), since the distribution may not be normal.(Zhou et al., 2019) We will share summaries of qualitative and quantitative results with the YAB after each usability cycle, to judge the feasibility, usability, and acceptability, and then adjust the intervention.

4. Sharing of Testing Results

We will not share results with the participants. However, we will be updating the patient's healthcare team (e.g., doctors, nurses, social workers) about their participation in this study once a week while participating in this study. For example, we may share information about barriers to taking medication or needs for extra support/information identified in the patient's response in the app or by talking/texting with the coach. Providing this information back to their medical team could improve their access to timely patient education, support, and other clinical services provided by the hospital.

5. Future Use of Data

For Phase I, the data collected in this study will be submitted to a data repository hosted on Open Science Framework (OSF). The OSF is a free and open source tool allowing researchers to share research material such as de-identified datasets to increase transparency in research. This may reduce fraudulent research by allowing other researchers to re-run analyses or check original data against published claims. The quantitative dataset will be available to the general public via the OSF website. The quantitative dataset collected in this study will be de-identified before being uploaded, with the participant identifier codes deleted from this version. Only responses to questionnaires/checklists.

6. Withdrawal of Subjects

- The PI may remove a participant from the study if they become extremely distressed, ill, or cannot complete study procedures. The PI will inform them they are being

removed from the study, provide referrals to resources such as behavioral health support or re-direct them to their subspecialty clinic.

- Participants will be allowed to withdraw from the study at any time. They can call or email the PI to request that they be removed from the study or tell us in person/virtually. They can stop using the intervention at any time and continue participating in the interviews, surveys, allowing us to record information from their medical record, and still receive compensation. Any data collected before withdrawing from the study will be analyzed, but no further data will be collected.

7. Provisions to Monitor the Data to Ensure the Safety of Subjects

This research does not involve more than minimal risk. However, we will monitor the data to ensure the safety of subjects, adhering to NIH guidelines.

Ongoing Data and Safety Monitoring. The principal investigator (PI) and a member of the mentorship team (either West, Wu, or Belzer) will convene at least monthly to monitor the conduct of the study. The agenda for these meetings will include, but not limited to, discussion of participant recruitment, enrollment and retention, data collection, issues around implementation, documentation and review of any concerns or adverse effects, and treatment adjustments. Minutes of these meetings will be recorded and archived in a Data and Safety Monitoring electronic folder. This meeting will ensure that the project proceeds on its timeline, and that any issues around the collection of data or the safety of study participants are discussed in a thorough and timely manner. The PI will record adverse events, unanticipated problems, serious adverse events, if any, after reviewing intervention data generated in the CIAS program and coaching calls/text recordings or transcripts on a weekly basis. The PI will submit summary reports every six months (i.e., two per year), based on this Data Safety Monitoring, to the mentor committee. All changes in protocol design will be reviewed by the IRB before such changes in protocol design take place.

Phase I Data Safety and Monitoring Board (DSMB). For this phase of study, the mentoring team (West, Wu, Belzer) functioned as the DSMB for this study. The DSMB met at regular intervals, not less than twice per year, and more frequently if deemed necessary. The DSMB for this trial: 1) reviewed twice yearly summary reports filed by the PI to the DSMB regarding the conduct of this study (as noted above); and 2) reviewed the nature of any serious adverse event that occurs during the trial, as it occurs during the trial (please note that serious adverse events will be reported to the DSMB within 5 business days from the time that the research team becomes aware of the event). The DSMB monitored recruitment, protocol deviations, adverse events, unanticipated problems, serious adverse events, and descriptive characteristics of the enrolled participants. The study personnel would have recorded adverse events at each participant contact, using both spontaneous reports and participant responses. However, no adverse events were detected during Phase I. DSMB members will summarize action steps, if any, and sign meeting minutes at scheduled and ad hoc meetings.

Potential adverse events. There are no known risks associated with the use of the cell phone support interventions or the self-report questionnaires associated with this study protocol, other than potential emotional discomfort discussed earlier and as described in the consent forms. However, potential adverse events not associated with the study protocol could include the

worsening of medication nonadherence, active suicidal intent, or life events that affect overall functioning. An adverse event will be defined as any event that occurs after informed consent for the study has been obtained, without regard to group assignment (e.g., onset of medical condition). A serious adverse event will be defined as an event that requires hospitalization, is potentially life-threatening, or results in chronic disability.

Consent Process and Process to Document Consent in Writing

Patient Participants
Participants will be consented either on the phone, via a CHLA approved HIPAA-compliant teleconference platform, or in person at CHLA. We are offering phone consent conferencing as an alternative to teleconferencing due to the lower level of technology literacy among some of our prospective participants and parents/guardians. Participants that will turn 18 years old while participating in this study will be consented for their continuing participation remotely.

If obtaining consent/permission/assent in person: We will use a private patient consultation room at the hospital. When in person, we will use paper forms for collecting wet signatures. For participants participating in the full study, written consent/permission/assent and HIPAA authorization (as applicable) will be documented and verbal consent/permission/assent will be obtained from those that declined participation in the full study but agreed to complete the research surveys only and from those that screen failed or decided not to participate in the study to retain their responses to the screening questions.

If engaging in a remote consent conference: We will send the link to the consent and HIPAA authorization forms (as applicable) prior to the start of the conversation and will confirm that they received them. They will be asked to review the forms and make note of any questions in advance of the conference. We will verify who we are speaking with by asking for the patient's name and DOB to ensure that the correct individuals are present for the consent conference. The consent conference will be completed via telephone or video conferencing (using a CHLA approved, HIPAA compliant platform) just as would occur in-person. For participants participating in the full study, they and their parent/legal guardian (as applicable) will be asked to sign and date all forms before ending their conference if they choose to participate in the study. Based on prior studies with comparable populations, we have found most participants and caregivers have smartphones that allow them to click on the consent link and sign with their finger. We will give them clear, step by step instructions on the phone call/video conference, which they will put on speaker phone, while they click through the consent pages. If any participant's parent/legal guardian indicates they do not understand how to sign electronically, we will give them an option to schedule an in-person meeting at CHLA with research personnel or to receive a paper copy of the consent form by mail with a stamped addressed envelope to provide a wet signature and return by mail. Instructions for returning the signed documents will be discussed. The person obtaining consent will sign immediately, as well. Each time the participants are sent a new link to the research questionnaires we will include a reminder that the study is voluntary and that they can contact the PI if they wish to withdraw, to ensure ongoing consent.

For those not participating in the full study, they will be asked to provide verbal consent/permission/assent for participation in the research surveys. In addition, verbal consent/permission/assent will be obtained from those that screen failed or decided not to participate in the study to retain their responses to the screening questions.

Full-text consent forms will be provided in English and Spanish; short forms will be used if parents/legal guardians speak a language other than English or Spanish. Qualified interpreters will be used if needed.

All participants

For all types of participants, we will follow the "SOP: Informed Consent Process for Research (HRP-090)" guidelines. We will also follow the SOP: Written Documentation of Consent (HRP-091) procedures, adapted for electronic signatures in the "Remote Consent for Research: Obtaining Consent and Documenting Consent (Electronic Consent)" guidelines. Specifically, we will use a CHLA approved, HIPAA compliant platform (e.g., DocuSign) to collect electronic signatures and dates from participants, and from the person obtaining consent, except for those parents/legal guardians that express they don't understand how to sign electronically as described above.

Designated members of the study team (e.g., the PI or the research assistants) will obtain consent/permission/assent and HIPAA authorization (as applicable), and all will be fully trained with modeling, didactic instruction, role-play, and live observation of initial consent meetings by the PI. The consent conference will be documented in the study files including the names of any witnesses and the means of communication. Copies of the signed consent forms (as applicable) will be provided to the participants and/or their parent(s)/legal guardian(s).

Also, we will ask the following questions to ensure their understanding, correcting any misconceptions they may state: (1) What are you being asked to do? (2) What question is this study trying to answer? (3) What are the potential risks of participating in this study? (4) How often will you need to come in for study visits? (5) What is the difference between participating in this study and your standard medical care? (6) What should you do if you decide to withdraw from the study?

All participants will be consented prior to the start of any study procedures or their continuing participation in the study (those turning 18 years old). We will schedule 30 minutes for the consent conference for all participants; however, additional time will be provided if potential participants need time and/or to discuss their participation with others in their lives.

For participants consented remotely, the electronic consent document/process allows subjects to proceed forward/backward or pause for review later. Subjects will have access to all of the consent forms via the links that will be maintained throughout the lifespan of the study. They may also contact the study team to obtain copies of the consent forms at any time.

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CHILDREN'S HOSPITAL LOS ANGELES
INFORMED CONSENT/PARENTAL PERMISSION/ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Adaptive Cell Phone Support to Promote Medication Adherence among Adolescents and Young Adults with Chronic Health Conditions

User Testing Group (Phase 1)

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

A person who takes part in a research study is called a research subject or research participant. If you are reading this consent form as a parent/legal guardian "you" also refers to "your child" (the research participant).

KEY INFORMATION
The information in this form is being used to seek your consent to participate in a research study. This section describes the key information that we believe most people need to know to decide whether to take part in this research. Later sections of this document will provide details of the research.

What should I know about this research?
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
Participation will last up to 3 weeks.

Why is this research being done?
This research is being done to create and test a phone-based system (phone program) to help adolescents and young adults take their medication(s) more consistently.

What happens to me if I agree to take part in this research?
Study procedures for this research are:
- Trying out a phone-based system (phone program) and allowing us to share user engagement data
- Completing surveys
- Participating in two audio-recorded interviews

- Allowing researchers to record information from your medical record
- Allowing your data to be stored for use in future research.
- Optional Procedure: Participate in phase 2 of this study in the future

Could being in the research hurt me?
- Feeling uncomfortable answering questions in the surveys and/or interviews.
- Having someone accidentally see your information who is not supposed to.

Please see the **POTENTIAL RISKS AND DISCOMFORTS** section below for a complete list of expected risks.

Will being in this research benefit me?
You may find that participating in the study will help you take your medication more consistently, due to receiving the phone support or coaching.

What other choices do I have besides taking part in this research?
As this is not a treatment study, the alternative is to not participate.

INTRODUCTION
You are invited to join a research study led by Caitlin Sayegh, PhD from the Divisions of General Pediatrics and Adolescent and Young Adult Medicine at Children's Hospital Los Angeles (CHLA). This research is paid for by the University of Southern California (USC), the Barbara Korsch Ward Foundation, and the Saban Research Institute.

You are invited to join this study because you are a CHLA patient between 15-20 years old taking at least one daily oral medication. Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

PURPOSE OF THE STUDY
The purpose of the study is to create and test a phone-based system (program) to support adolescents and young adults in taking their medication(s) more consistently.

NUMBER OF PARTICIPANTS
Approximately 192 people will be asked to take part in this study at CHLA.

LENGTH OF PARTICIPATION
Your participation in this study will last 3 weeks.

PROCEDURES
If you volunteer to be in this study, we will ask you to do the following things:

- **Phone-based program Trial Period**: Try out the program for 3 weeks. This will include accessing the program on your phone 3-5 times per week to check in about your medication-taking, identify barriers and solutions to taking your medication(s), and learn about resources that could help you stay on track with taking your medication(s) more consistently. This program will also include access to a human coach, who you can communicate with through in-program messages, texts, or phone calls. You will not need to download the program onto your phone. We will send you a link to the program that you can click on to open the program on an internet webpage. It is always your choice whether you wish to click on the link and participate that day.

- **Human Coaches**: Coaches will reach out to introduce themselves at the beginning of the three weeks, to update you on your progress in the phone-based system halfway through the three weeks, and to let you know at the end of the three weeks that the trial period is over. A short video explaining coaching will be provided to you. Additionally, the coach may reach out to you (e.g., after missing medicines) and/or you may request support from a coach through the phone program. Interactions with coaches will last about 5 minutes but could last longer and all phone calls will be audio-recorded. All audio recordings and text messages will be reviewed and if incorrect information is given to you by the coach, they will contact you (e.g., by phone, text) to provide you with the correct information. You may choose not to answer calls or text messages from the coach.

- **Interviews**: Participate in two audio-recorded interviews with a research team member. The first interview will happen before the 3 week trial period and involves introducing the phone program to you and discussing your initial thoughts about the program. The second interview will happen after the 3 week trial period and involves discussing your opinions and experiences about using the phone program. The interviews may be held in person or virtually via a video-conferencing platform, scheduled at your convenience. Each interview will last about 60 minutes but could be longer depending on the discussion.

- **Surveys**: Complete on-line surveys after each interview. If meeting in person, the surveys will be provided to you on a laptop, and if meeting virtually, a link to the surveys will be provided to you in the chat function. In these surveys, you will be asked questions about your demographics (e.g., gender, race/ethnicity, highest educational level, etc.), your medication-taking, acceptability of the phone program (e.g., how acceptable would it be to use, etc.), and your opinions about the phone program (e.g., ease of use, etc.). It will take about 15 minutes to complete these surveys.

- **Sharing of User Engagement Data:** A summary of user engagement data from the phone program (e.g., frequency of use, duration of use, etc.) will be shared with our Youth Advisory Board (YAB) so that adjustments/improvements can be made to the program. The YAB is a group of people that are helping us design this study. None of your identifying information will be shared with them.

- **Chart Review**: Allow the researchers to record information from your medical chart for the year before joining the study. We will record information such as your medical condition(s), which medication(s) you are prescribed, the instructions for taking those medications(s), lab results, appointment information (e.g., date of appointment, type of appointment, etc.), and hospitalization information (e.g., date of hospitalization, length of stay, reason for hospitalization, etc.).

- **Repository**: Some of the data collected in this study will be stored in a repository hosted at Open Science Framework (OSF). A repository is a “bank” or “library” of data collected from many people and provides a way for researchers to conduct future research (see the FUTURE RESEARCH USE OF DATA section below for further details). The data that will be stored includes responses to surveys and a summary of scores we calculate based on information recorded from your medical records (e.g., percentage of days medication was in each participant’s possession). The data will be stored in this repository indefinitely.

- **Optional Procedure**: You have the option to participate in phase 2 of this study at the end of your participation in phase 1 and if you still qualify for participation. Phase 2 of this study involves being assigned to either use the phone program or to receive automated text messages, completing surveys, and allowing us to record information from your medical record. Participation would last one year. Complete

details about phase 2 of this study will be discussed with you and you will be asked to sign a separate form for phase 2 of the study if you are interested in participation. You can let us know your decision at the end of this form. You may still participate in phase 1 of this study even if you do not want to participate in phase 2.

POSSIBLE RISKS AND DISCOMFORTS
You may find the phone program annoying or unhelpful.

You may feel uncomfortable answering questions in the interviews and/or in the surveys. You may skip or stop answering any questions that make you uncomfortable. Text messaging is a form communication that is not as secure as talking on the phone. The cell phone carrier for the coach and for you may be able to access the text messages sent back and forth between you and the coach. To prevent risks to your privacy, the coach will avoid typing your name, diagnosis, medication name, or other identifying information, and we encourage you to do the same. This is a voluntary study, so if you are not comfortable with this, please decline to participate.

It is possible that you may reveal that you are experiencing mental health struggles including having thoughts about harming yourself or others to the coach that may require medical attention. If this happens, this will be considered a potential psychiatric emergency and you will be contacted. A psychologist/psychiatrist (either a member of the study team or an on call psychologist/psychiatrist) will be notified and details about the situation will be shared with the them so that they can determine if you are in need of an urgent psychiatric assessment. If you are less than 18 years old, your parent/legal guardian may also be notified if we are unable to get in contact with you; however, this will be at the discretion of the psychologist/psychiatrist.

If it is determined that you are in need of an urgent psychiatric assessment, you will be asked to go to the nearest Emergency Department (ED). The psychiatrist will assess you, and if necessary, will facilitate transfer to an appropriate inpatient psychiatric facility from the ED according to routine hospital procedures. If you do not present an immediate threat to yourself but are in need to mental health services, the psychiatrist can assist in determining the appropriate outpatient psychiatric resources, either by referring you to mental health services provided by your insurance, or referring you to the Los Angeles County Department of Mental Health (800-854-7771) to locate the closest mental health clinic to your home.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).

POSSIBLE BENEFITS TO SUBJECTS
You may find that participating in the study will help you take your medication more consistently, due to using the phone support tool or receiving coaching.

POSSIBLE BENEFITS TO SOCIETY
This study may help the researchers learn more about effective ways to help adolescents and young adults take their medication(s) more consistently. Hopefully, this study will result in a helpful phone support tool (phone program) for adolescents and young adults with chronic health conditions.

YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY
The alternative to participation is to not participate in this study.

COSTS TO YOU FOR BEING IN THIS STUDY
If you attend an in-person interview with the research team at the hospital you may incur metro, gas, or parking fees that are not covered by the study. The phone support tool (phone program) and coaching will be delivered to your personal phone, so you may be charged for data, texts, or calls by your cell phone carrier. The study does not cover these costs for you.

PAYMENT FOR PARTICIPATION
For taking part in this research, you will be paid up to a total of $80. You will be paid $40 after each interview via a debit card (ClinCard). The card will be provided to you after the first interview either in person or mailed to you if the interview is done virtually, and we will remotely load the additional $40 after the second interview. You should let us know if you lose the card so that we can transfer the remaining funds to a new card and mail it to you.

CONFIDENTIALITY
The data collected as part of this study will be “coded.” Coded means that the data collected for this study will be assigned a unique code or Study ID. Your research data will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data.

People on the research team will know that you are in this research study. All results will be kept confidential. User engagement data from the phone program (e.g., frequency of use, duration of use, etc.) will be shared with our Youth Advisory Board (YAB) so that adjustments/improvements can be made to the phone program as described in the PROCEDURES section above. Only “de-identified” or “anonymized” data will be shared with the YAB. This means that there will be no way to link the user engagement data back to you.

In addition, we will be updating your healthcare team (e.g., doctors, nurses, social workers) about your participation in the study once a week while you are participating in this study. For example, if you share information about barriers to taking your medication(s) or needs for extra support or information, either in your responses in the phone support program or when talking or texting with the coach, we will share this information with a member of your healthcare team so that they can help you access hospital resources (e.g., patient education, support, other clinical services, etc.).

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:

- The CHLA Institutional Review Board (IRB) that reviewed this research, and authorized representatives of CHLA.

The audio-recordings made of you during this study will not be shared outside the research team. The transcripts produced from the audio recordings will not include any identifiable information (e.g., names, etc.). The audio-recordings will be destroyed once the research data has been analyzed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

The results of the research may be presented or published. We will keep your name and other identifying information confidential.

FUTURE RESEARCH USE OF DATA

The data collected as part of this study will be “anonymized” when stored in the repository. This means that there will be no way to link the data back to you. Once your data have been anonymized, they may be used by the researcher conducting this study, the study sponsor, or other researchers (at CHLA or elsewhere) for future research

projects that are unrelated to the purpose of this study. This future research may be done without consulting you or obtaining consent (permission) for this additional use.

STUDY WITHDRAWAL
The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you become extremely distressed, if you do not follow instructions, if you cannot complete study procedures or if you miss scheduled visits. We will let you know if we are ending your participation in this study and if applicable, we will provide you with referrals to resources (e.g., behavioral health support, etc.). The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about/from you up to that point will remain part of the study for analysis and may not be removed from the study database. However, no additional data will be collected from/about you. In addition, we will be unable to remove your data from the repository since it will be anonymized.

QUESTIONS ABOUT THE STUDY
If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, Caitlin Sayegh, PhD, at 323-361-7748. You may also contact the research team through email at DASHLab@chla.usc.edu.

ClinicalTrials.gov is a Web site that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This research is being overseen by the CHLA Institutional Review Board ("IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or hspp@chla.usc.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

RIGHTS OF RESEARCH SUBJECTS
You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know by calling and/or emailing her or letting her know in person/virtually.

You can stop using the phone program at any time and just complete the other research procedures (i.e., interviews, completing the surveys, allowing us to collect information from your medical records).

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked to sign a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from CHLA.
- If you decide not to take part, you can still receive medical care from CHLA.
- You will be given a copy of this signed and dated consent form to keep.
- You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.

OPTIONAL PROCEDURE

Would you be interested in being invited to participate in phase 2 of this study that involves testing the phone program again in the future? Please provide your initials beside your decision.

_____Yes _____No [Subject]

_____Yes _____No [Parent/Legal Guardian (for children)]

SIGNATURE OF RESEARCH SUBJECT

(*For adults who are capable of providing consent; children ages 14 to 17 years old who are capable of providing assent*)

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)
(*For all subjects under the age of 18*)

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; 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.

Assent Instructions: All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.

Subjects ages 15 to 17: If assent is obtained, have the subject sign this consent form, unless the investigator determines that the subject is not capable of signing.

☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____

Print Name of Individual Obtaining Consent

_____ _____

Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- You were present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in your presence.

_____

Print Name of Witness

_____ _____

Signature of Witness Date