CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

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This form is for new projects that have not been previously approved by CPHS.

Data entry
- Submitted 04/08/2025 1:24 PM ET by Kimberly Miller, PhD

Amendment Header

Amendment Submitter

April 2025 cycle

02/26/2025 • Nicholas Zadrozna • Internal

Kimberly Miller, PhD

Email: kim.miller@med.usc.edu **Business:** (323) 865-0674

Instructions for amending your approved application:

This is a copy of the project application in order to amend the project. You must answer all the amendment questions. After you've answered those questions, you will have to update all answers on the form that related to your proposed changes. You may leave other questions with their original answer. If you do not update the appropriate responses on the form related to your proposed amendment, you will be required to make additional changes.

Note that the contacts listed on this page are output only questions that cannot be changed. If you need to request personnel changes, you will be prompted later on within this form to enter the new contact information.

PI:

Katie Devine, PhD

Email: katie.devine@rutgers.edu **Business:** (732) 235-7549

Administrative Contacts:

Name	Role
Laura Thompson, MA	Administrative contact

Protocol Number:

2023-190

Protocol Title:

Digital Self-Management and Peer Mentoring Intervention to Improve the Transition from Pediatric to Adult Health Care for Childhood Cancer Survivors

Indicate what types of changes you are requesting to this project. Select all that apply

Other (examples such as, but not limited to: budget changes, project site and project title)

Clearly summarize and justify your proposed changes to the protocol in layman's terms for all selections made above

Please provide a summary of the "additions and edits" to the survey measures and provide a justification for these changes. Why are they necessary? The changes to the surveys do not seem minor, they appear to be fairly extensive. Many of the changes do not seem to be at all related to the stated purpose of the study, which is to test the success of your intervention in helping individuals transition to self-management of their cancer survivorship. In particular, it is not at all clear why you need to ask questions about behaviors such as exercise, alcohol consumption, cigarette smoking, cannabis use, etc., or questions about non-cancer related access to routine and preventive medical services (e.g., screening mammograms, ECGs, pap tests), dentist visits, etc.

03/04/2025 • Laura Lund, MA • *Not* Internal

Please provide a summary of the “revisions and edits” to the participant eligibility screener and provide a justification for these changes. Why are they necessary?

03/04/2025 • Laura Lund, MA • *Not* Internal

Please describe the ‘edits to participant communication’ and provide a justification for these changes.

03/04/2025 • Laura Lund, MA • *Not* Internal

Please provide a summary of the changes made to the ICF and provide a justification for the changes.

03/04/2025 • Laura Lund, MA • *Not* Internal

Please provide a summary of the changes made to the recruitment flyer and provide a justification for the changes.

03/04/2025 • Laura Lund, MA • *Not* Internal

Please provide a summary description of the website you are proposing, its purpose, and a justification for including this change in your study.

03/04/2025 • Laura Lund, MA • *Not* Internal

The purpose of this amendment is to make changes in the following areas in preparation for recruitment launch:

1) change of personnel (new administrative contact, co-PI, and RO)

2) additions and edits to survey measures

3) revisions and edits to participant eligibility screener

4) edits to participant communication

5) edits to Informed Consent Form

6) edits to recruitment flyer

7) addition of participant website

Thank you for your review. Please see answers to contingencies below:

- *Please provide a summary of the "additions and edits" to the survey measures and provide a justification for these changes. Why are they necessary? The changes to the surveys do not seem minor, they appear to be fairly extensive. Many of the changes do not seem to be at all related to the stated purpose of the study, which is to test the success of your intervention in helping individuals transition to self-management of their cancer survivorship. In particular, it is not at all clear why you need to ask questions about behaviors such as exercise, alcohol consumption, cigarette smoking, cannabis use, etc., or questions about non-cancer related access to routine and preventive medical services (e.g., screening mammograms, ECGs, pap tests), dentist visits, etc.*
    - While transition readiness is the primary focus of the study, a secondary focus is behaviors related to positive self-care and health promotion as survivors. The 5th module of the intervention focuses specifically on health behaviors, including exercise, alcohol consumption, tobacco use, cannabis use, etc. Routine and preventive medical services (such as mammograms, EKGs, pap tests) are also an important part of survivorship care, are part of counseling by healthcare providers for childhood cancer survivors, and recommended as part of the intervention. Therefore, we believe it is important to evaluate any change in these behaviors due to the intervention.
- *Please provide a summary of the "revisions and edits" to the participant eligibility screener and provide a justification for these changes. Why are they necessary?*
    - Added clarifying information and examples in eligibility questionnaire to ensure potential participants are able to answer accurately. This includes more specific language (ie instead of "others", "new medical providers and other people when needed") and more concrete examples (ie added "having a copy of your insurance card or online account access, being able to give insurance information at appointments" to a question regarding health insurance knowledge). Added new text for communicating ineligibility and minor grammar and clarity edits. The edits and additions were made to ensure better understanding of the screening questions by prospective participants.
- *Please describe the 'edits to participant communication' and provide*

a justification for these changes.

- Additions include links to online surveys, information on downloading and installing the study app, information regarding weekly topics, and email verbiage for participants in the intervention arm. These were added or edited to better highlight information for participants, particularly adding the correct links for participants as they have been finalized since initial study approval.

- *Please provide a summary of the changes made to the IC and provide a justification for the changes.*
  - Edited to add language consistent with current USC consent form including information on PI contact, sponsor, participant inclusion, length of study, benefits, alternatives to participation, incentives, confidentiality, storage and use of PII, future data use, and future contact options. Additional minor edits were made (indicated on the submitted tracked changes document) for grammar and clarity. Edits, deletions and additions were done to provide more complete and clear information to prospective participants.
- *Please provide a summary of the changes made to the recruitment flyer and provide a justification for the changes.*
  - Additional information about study program options, USC contact information, and the informational website link were added. The overall design was refined and copy edited for legibility and clarity based on feedback from patient advocates.
- *Please provide a summary description of the website you are proposing, its purpose, and a justification for including this change in your study.*
  - The website is an informational resource for potential participants. It is a broad overview introducing the study and research team, outlining what a participant could expect through their participation. It reiterates and expands on the initial information given during a recruiting call and email and is designed to reinforce the legitimacy of the study for participants. We recognize that some people prefer to take in information at their own pace and the website is an always-available resource for this. Additionally multiple modes of contact information are provided should a prospective participant need them.

Indicate the Level of Risk involved with the changes proposed.

If level of risk has changed, please update the "Risks" section in the protocol form.

Level of Risk has not changed

PI City Output *(Internal)*

New Brunswick

PI Location State Output *(Internal)*

New Jersey

Personnel Information for Amendment

Please complete the questions below.

If while trying to complete those questions, personnel are not found by their email address, you can add them in the system by completing the 'new contact form'. Click on the form and complete it. Within a few minutes of completing the form you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

New Contact Form

Existing Personnel

Name	Role
David Freyer	Co-Principal Investigator
Howard Hu, ScD	Responsible Official
Katie Devine, PhD	Principal Investigator
Kimberly Miller, PhD	Co-Principal Investigator
Kristine Levonyan-Radloff, MA	Research Team
Laura Thompson, MA	Research Team
Laura Thompson, MA	Administrative contact
Margaret Masterson, MD	Co-Principal Investigator
Pamela Ohman-Strickland, PhD	Co-Principal Investigator
Priscilla Marin, BS	Research Team
Shengguo Li, PhD	Research Team

Will you be making any changes to the makeup of research personnel?

Add new Administrative Contacts
Addition of Co-Principal Investigators
Change in Responsible Official
Removal of any research personnel

Please enter the email address(es) of the new administrative contact(s)

If you are removing an administrative contact, remember to include that individual in the 'removal of personnel'.

Jonathan Kaslander, M.Arch
Email: Jonathan.kaslander@med.usc.edu **Business:** +1 (323) 442-8207

Please click 'Add Contact' and add the email address of any new co-principal investigators

Scott Moerdler, MD
Email: scott.moerdler@rutgers.edu **Business:** (732) 235-2465

Additional document is required, please upload CVs.
Rutgers CV Moerdler_Jan 2025.pdf Co-PI Curriculum Vitae

Please enter the email address of the new Responsible Official.

Include previous Responsible Official under personnel to remove below.

Ricky Bluthenthal, BA, MA, PhD
Email: ricky.bluthenthal@med.usc.edu **Business:** (323) 442-8236

REMOVE CONTACT(S)

Click 'Add Contact' button to enter in the email address of any staff (including co-PI or RO) from the above list that are being removed from the study.

Laura Thompson, MA
Email: lkthomps@usc.edu **Business:** (865) 386-6622
Howard Hu, ScD
Email: Howard.Hu@med.usc.edu **Business:** (323) 865-0803
Margaret Masterson, MD
Email: masterma@cinj.rutgers.edu **Business:** (732) 235-8864

Project Information

SUBMITTER

Application completed by:

Kimberly Miller, PhD
Email: kim.miller@med.usc.edu **Business:** (323) 865-0674

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

Digital Self-Management and Peer Mentoring Intervention to Improve the Transition from Pediatric to Adult Health Care for Childhood Cancer Survivors

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

Data Registry
Program Evaluations
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

Common rule/Human subjects

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

If the research does not involve any of following, choose "None of the above."

Minimal Risk
Consent form

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."
Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Not applicable

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
National Cancer Institute, National Institutes of Health

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

For a list of public meeting dates, see the CPHS website

12/01/2023

ANTICIPATED PROJECT END DATE

06/30/2029

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

Childhood cancer survivors are at risk for adverse late health effects from treatment, including cardiovascular disease, neurocognitive problems, and mental health conditions. Survivors require lifelong "risk-based" follow-up care based on the treatment they received to identify and treat late health effects. Unfortunately, less than 1 in 5 adult survivors of childhood cancer obtain risk-based follow-up care, and survivors who identify as Hispanic are less likely to do so. The transition from pediatric to adult follow-up care is a critical period when many survivors are lost to follow-up. Barriers to successful transition include poor knowledge of cancer history, low healthcare self-efficacy, poor self-management skills, low health literacy, and access issues such as financial hardship, insurance, and distance from cancer center.

There are no efficacious interventions that specifically target this transition for young adult childhood cancer survivors (YA-CCS), and prior studies have been limited by narrow focus on knowledge or specific health behaviors, suboptimal engagement with digital platforms, and failure to attend to social needs of AYA. The purpose of the study is to determine the efficacy of the Managing Your Health intervention to improve self-management of survivorship care among young adult survivors of childhood cancer. Managing Your Health will be tested in a two-arm parallel randomized controlled trial (RCT) of the intervention versus usual care + educational control. Managing Your Health intervention consists of six weekly videoconference calls with a peer mentor and five self-management educational modules within a mobile application. The Usual Care group will receive weekly emails and SMS messages with links to the Health Links developed by the Children's Oncology Group for use in survivorship care. The study will be conducted at two sites: Rutgers Cancer Institute of New Jersey (primary) and the University of Southern California. YA-CCS will be recruited through the New Jersey State Cancer Registry (NJSCR) and the Los Angeles Cancer Surveillance Program. Peer mentors (hired staff) will be recruited from the Children's Hospital Los Angeles and Rutgers Cancer Institute of New Jersey.

Rutgers Cancer Institute of New Jersey has obtained IRB approval for this study from the Rutgers Institutional Review Board. Rutgers is approved for use of cancer surveillance data and the New Jersey State Cancer Registry is housed at Rutgers.

MAJOR RESEARCH QUESTION

What is the major research question to be addressed in this project?

The purpose of the study is to determine the efficacy of the Managing Your Health intervention to improve self-management of survivorship care among young adult survivors of childhood cancer.

A. Objectives
The primary objective is to evaluate the efficacy of the intervention.

B. Hypotheses/ Research Question(s)
Aim 1: Evaluate the efficacy of the Managing Your Health intervention.
Hypothesis 1: Participants in the Managing Your Health intervention will demonstrate greater self-management behaviors compared with controls.
Hypothesis 2: Participants in the Managing Your Health intervention will demonstrate greater adherence to guideline-concordant survivorship care and better quality of life at 12 months post-randomization.

Aim 2: Determine the mechanisms through which Managing Your Health influences outcomes.
Hypothesis 3: Outcomes are mediated by increased knowledge, healthcare self-efficacy, emotion self-regulation, and social support.

Aim 3: Identify subgroups of participants for which treatment effects vary to inform future scale up.
Hypothesis 4: Effects will be stronger for those who identify as Hispanic, have lower health literacy, experience financial hardship, and live further from their cancer treatment center.

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

Because your study is fairly complex please clearly describe the specific changes in procedures that you propose in this amendment at the end of the original study procedures description, using a heading such as: 'amendment March 2025', so that reviewers can understand what you are proposing to change/add and how the changes will modify the original study design.

03/04/2025 • Laura Lund, MA • *Not* Internal

You have provided a document describing patient contact procedures. In your amendment update to the study procedures section, please provide a description of any changes in the proposed contact procedures that are different from those originally approved for the study. Please provide any materials that are referenced in this description document that you are requesting approval for in this amendment. I was not able to click on links for any items that appeared to be changed to get to the referenced documents. I am not able to tell from the submitted materials what is new and what was previously approved.

03/04/2025 • Laura Lund, MA • *Not* Internal

1. Research Design and Methods
Managing Your Health will be tested in a two-arm parallel randomized controlled trial (RCT) of the intervention versus usual care + educational control. Managing Your Health intervention consists of six weekly videoconference calls with a peer mentor and five self-management educational modules within a mobile application. The Usual Care group will receive weekly emails and SMS messages with links to the Health Links developed by the Children’s Oncology Group for use in survivorship care. Access to these Health Links reflects the current state of clinical care available to survivors. These Health Links were developed as patient education materials to cover relevant self-management and survivorship care topics.

1.1. Research Procedures
YA-CCS will be recruited through the New Jersey State Cancer Registry (NJSCR, Rutgers site) and the Los Angeles Cancer Surveillance Program

(LACSP, USC site). After informed consent and signature of medical release forms to obtain medical records, participants will complete an online baseline survey using REDCap, a HIPAA-compliant electronic data capture system (for USC participants we will use USC's REDCap). Next, participants will be randomly assigned to the intervention or usual care + educational control group (described in section 4). A randomization scheme will be determined using an undisclosed varying block size of 4 to 6 to ensure balance in sample size between groups. We will stratify randomization by ethnicity (Strata: Hispanic/Latino ethnicity or not Hispanic/Latino ethnicity) and sex, as there is evidence to suggest that Hispanic survivors and males engage in survivorship care at lower rates. Research staff will notify survivors of assignment via phone, text, and/or email. All participants will be asked to complete surveys again at 3 and 12 months. At 12 months, participants will be asked to update the medical release with any new providers.

An outline of our patient contact procedures is attached (MYH USC Patient Contact Procedures_revised_02.06.2024_tracked.docx).

1.2. Data Points
All participants will be asked to complete a baseline survey and follow-up surveys at 3 months (post intervention) and 12 months (9-month follow-up). Surveys include patient-reported outcomes related to self-management skills, healthcare utilization, health-related quality of life, knowledge, healthcare self-efficacy, self-regulation of emotions, and social support. Medical record data regarding healthcare utilization will be collected/abstracted with patient permission (i.e., medical release forms/HIPAA authorization). Study staff will also collect data regarding participant completion of intervention sessions and peer mentor fidelity. Intervention sessions will be audio-recorded with participant permission for fidelity evaluation, analysis of sessions, and peer mentor supervision.

1.3. Study Duration
The overall study will last 5 years. Each subject will participate for 1 year.

1.4. Endpoints
The primary outcome is self-reported self-management behaviors. Secondary outcomes include adherence to guideline-concordant survivorship care and health-related quality of life.

2. Preliminary Data
Development of the Managing Your Health Intervention. This proposal builds from a series of preliminary studies to identify AYA survivors' unmet needs, illuminate intervention topics relevant to the conceptual framework, identify optimal delivery approaches, and demonstrate feasibility of the peer mentorship model and online modules. In brief, we conducted formative research in three stages: (1) formative interviews with AYA survivors that identified barriers and facilitators to obtaining risk-based care and transitioning from pediatric to adult care; (2) content development to define the essential components of the intervention; and (3) refinement of initial content and prototype of the intervention. Results indicated five key self-management topics for education and the need for a peer mentor to provide

specialized support given shared lived experience. Thus, the Managing Your Health intervention consisted of six videoconference calls with a peer mentor and five online self-management modules. The first call was to get to know each other, share survivorship stories, identify self-management strengths and weaknesses, and select goals for participation in the intervention. The remaining five weekly calls covered a self-management topic each week, including understanding one's survivorship care plan, navigating the healthcare system and insurance, negotiating family and significant other involvement in care, managing the emotional aspects of survivorship, and engaging in healthy lifestyle behaviors.

Feasibility and Acceptability of Managing Your Health Intervention.
We conducted an initial single-arm feasibility trial with 20 AYA survivor participants (ages 18 to 25 years) and 10 trained peer mentors (ages 21-29 years; NCT02699996). Fifteen survivors (53% female; M age = 22.1 years) were matched with a peer mentor and completed the 6-week intervention. On a scale from 1-5, participants reported high satisfaction with the program overall (M = 4.2, SD = 0.86), the online modules (M = 3.8, SD = 1.01), and discussions with their peer mentor (M = 4.6, SD = 0.63). Participants demonstrated significant improvements in transition readiness, $t(14) = 3.57$, $p < .01$, $d = 0.92$. However, they also suggested improvements in the online modules to make them more interactive and engaging, such as videos, narrated presentations, and tailored feedback, in line with the broader literature on user engagement Based on these promising results, we obtained an NCI R21 award (R21CA222936; NCT04075734) to create an interactive mobile responsive website to deliver the self-management modules. We used TigerConnect services to provide secure messaging and videoconferencing for participants and mentors. We evaluated the feasibility, acceptability, and preliminary outcomes of Managing Your Health through a randomized two-arm trial comparing the intervention to usual care. We recruited 50 AYA survivors and 10 mentors through the New Jersey State Cancer Registry and the CINJ long-term survivorship clinic. Feasibility and acceptability results were strong, meeting every threshold set a priori. At the 12-month follow-up, we retained 45 of 50 participants (94%). Of the 25 participants randomized to Managing Your Health, 22 (88%) completed all of the online modules and peer mentor calls. Of those 22, participants completed over 96% of the modules on average and 97% of peer mentor calls, which lasted on average 16-20 minutes each. Participants rated Managing Your Health as highly acceptable on the Treatment Evaluation Inventory-Short Form, with an average rating of 37.95, SD = 5.40 (note: scores >27 indicate moderate to high acceptability, with a maximum of 45). On a scale of 1 to 5, with 5 indicating the highest satisfaction, participants rated their overall satisfaction as high (M = 4.64, SD = 0.49), including the online content (M = 4.41, SD = 0.59) and their discussions with their peer mentors (M = 4.64, SD = 0.49). Although not powered to evaluate efficacy, we found self-management outcomes improved in the expected direction. That is, relative to the Usual Care control group, Managing Your Health participants demonstrated significant improvements in overall transition readiness (incorporating self-management skills, motivations, and goals), $z = 2.6$, $p = .01$. Participants in the intervention also showed improvements in knowledge ($p = .03$) and healthcare self-efficacy (ps = .02 to .29). Despite high satisfaction and acceptability, there were some suggestions to improve

the web-based self-management modules.

Adaptation of Managing Your Health for the Current Digital Generation. Results of the two-arm randomized feasibility trial indicated high acceptability and satisfaction, but also identified two opportunities for optimization from user feedback: (1) enhance access through a mobile app and (2) enhance interactive components within the modules. In partnership with Radiant Digital, we obtained funding to convert the web-based modules into a mobile application for iOS and Android (SBIR 75N91021C00053). We first conducted key informant workshops with AYA survivors, patient advocates, parent advocates, and healthcare providers to identify the key barriers to successful transition and prioritize design features for the app. Integrating these perspectives, we designed the prototype Managing Your Health app that onboards users with a survey to tailor content most relevant to the user, incorporates additional videos, graphics, and user prompts to enhance engagement with content, and allows users flexibility in selecting additional content for a 'deeper' dive into material of interest. We then recruited a racially and ethnically diverse sample of 25 AYA survivors with different childhood cancer diagnoses to download and test the app on their own devices. Usability testing sessions involved prompts to complete specified tasks as well as user exploration of different features of the app. We also asked users to rate the app on the System Usability Scale, a widely used rating scale regarding technology acceptance, perceived usefulness, ease of use, and intention to use the system. The average score was 80 out of 100, which is categorized as "Excellent" and well above the industry average of 68 across a wide range of apps. Users overwhelmingly endorsed the app as useful and easy to use, reporting strong intent to use the system if available. Users identified some minor changes that could optimize the app; we propose to make these final changes in this study prior to launching the randomized trial.

3. Sample Size Justification
We plan to enroll 300 young adult survivors of childhood cancer currently 18-25 years old (150 from the NJ State Cancer Registry and 150 from LA Cancer Surveillance Program/California Cancer Registry). Although our pilot had 90% retention at 12 months, we plan for up to 20% drop out, for an evaluable sample of 240. Power calculations for Aim 1 focused on the primary outcome, self-management behaviors. Our pilot study demonstrated a Cohen effect size of 0.54 for overall self-management score at follow-up when comparing the intervention and control groups. Using a two-sided alpha of 0.05, we would have >95% power to detect such an effect, which would be considered clinically meaningful. Even if the effect size is lower, we would have adequate power: if the effect size is only 75% of the pilot effect (at 0.40), we would have 88% power; if the effect size is only 67% of the pilot effect (at 0.36), we would have 80% power. We also have sufficient power to detect the effect of intervention on the secondary outcomes, quality of life and adherence to guideline-concordant survivorship care. For quality of life, we could detect effect sizes as small as 0.38 with 85% power. For guideline-concordant care, when comparing the averages of proportion of recommended care obtained for individuals between treatment arms, such that we observe a standard deviation of approximately 0.210 (observed in a similar study of adult cancer survivors at CINJ, R01CA176838, with

similar number and variation in eligible services, data not shown), our proposed sample size of 240 evaluable participants will allow us to detect a difference in average proportions as small as 0.082 with 85% power. For Aim 2, we have 80% power to detect knowledge as a mediator between the intervention and self-management behaviors, assuming we observe the same effect between intervention and knowledge as observed in our pilot study (~0.54), assuming baselines comparable between treatment arms) and an effect size between knowledge and self-management that is at least halfway between small and medium Cohen effect size (i.e., 0.26).21 For Aim 3, suppose that we examine the moderating effect of health literacy (which is dichotomized so that 50% has higher and 50% lower health literacy). Then we have 80% power to detect a difference when intervention effect sizes are 0.16 versus 0.52 when stratifying by health literacy.

4. Study Variables

4.1. Independent Variables, Interventions, or Predictor Variables
Intervention: The Managing Your Health intervention consists of six weekly videoconference calls with a peer mentor and five self-management educational modules within a mobile application. The first call is to get to know each other, share survivorship stories, identify self-management strengths and weaknesses, and select goals for participation in the intervention. The remaining five weekly calls cover a self-management topic each week, including understanding your survivorship care plan, navigating the healthcare system and insurance, negotiating family and significant other involvement in care, managing the emotional aspects of survivorship, and engaging in healthy lifestyle behaviors.

The Usual Care + Educational Control group will receive weekly links via email and SMS message to the Health Links developed by the Children's Oncology Group for use in survivorship care. Access to these Health Links reflects the current state of clinical care available to survivors. These Health Links were developed as patient education materials to cover relevant self-management and survivorship care topics. The weekly messages will align with the content of the modules from Managing Your Health to provide similar information, including Introduction to Long-Term Follow-Up (Module 1), Finding and Paying for Healthcare (Module 2), Emotional Issues (Modules 3 and 4), Educational Issues, Diet and Physical Activity, Skin Health, Reducing the Risk of Second Cancers, and Male/Female Health Issues (Module 5).

Predictor variables: Health literacy, financial hardship, and demographic factors will be collected as potential moderators of treatment effects. (see Section 5 Study Instruments for details).

4.2. Dependent Variables or Outcome Measures
Outcomes include self-management behaviors (primary), adherence to guideline-concordant survivorship care (secondary), and health-related quality of life (secondary). We will also measure potential mediators (i.e., knowledge, healthcare self-efficacy, self-regulation of emotions, and perceived social support), as well as measures of treatment integrity and intervention engagement.

See Section 5 Study Instruments for details.

5. Data Collection

Note: Data from USC/CCR will be kept at USC and NOT shared with Rutgers until after we have submitted an amendment providing a data security letter from Rutgers and receiving CPHS approval for the amendment.

5.1. Primary Data Collection

Location:
The survey link will be emailed and/or texted to the participant who can complete it at time/place they prefer on a computer or any other mobile device (i.e., phone, ipad).

Process of Data Collection:
Surveys will be administered online using REDCap, a HIPAA-compliant electronic data capture system. In the unlikely event of significant technical difficulties, paper copies may be mailed to participants with a postage-paid return envelope.

Timing and Frequency:
Surveys will be administered at baseline, 3 months (post-intervention), and 12 months (9-month follow-up). We anticipate each survey will take approximately 25 minutes.

Procedures for Audio/Visual Recording:
Participants will be asked to give permission to audio record the intervention sessions for evaluation of treatment integrity and supervision of the peer mentors. As part of the consent process, participants will be told that it is completely voluntary to agree to the recording and they can change their mind at any time. Peer mentors will be trained to also ask the participant if it is okay to record at the beginning of each session. It will not be considered a protocol violation if technical issues prevent or disrupt the recording or a mentor forgets to record a session. Digital recordings will be initially saved on secure local computers at USC and transferred to the main site (Rutgers) as soon as possible following each session to the study folder on a cloud-based file storage application for a secure storage, management and sharing of digital files (e.g., Rutgers OneDrive, site-specific platform) and then erased from other means it was recorded to. Recording will be labeled with a subject number rather than any identifiable information. Session audio recording files may be securely transferred between the members of the research team using a site-specific secure file transfer methods (e.g., Rutgers OneDrive file sharing feature).

Study Instruments:
Measures include:
Self-Management behaviors (primary). The Self-Management Skills scale is a 15-item measure about a patient's active behaviors in managing their health. Response options were modified such that participants respond on a

5-point scale from 1 (not at all) to 5 (completely) regarding their agreement to each item. Example items include "I participate in making decisions about my health" and "I book my own doctor's appointments." Validation with a sample of 250 AYA indicated that the scale is reliable (= .81) and valid. A total mean score will be used, which could range from 0 to 5. Higher scores indicate better self-management behaviors. (Baseline, 3 months, 12 months)

Adherence to guideline-concordant survivorship care (secondary). Adherence to guideline-concordant care will be measured by patient report and confirmed by medical record abstraction. At baseline and 12-months, participants will report on cancer diagnosis and treatment history, risk of late effects, cancer-specific and general medical appointments, surveillance tests, cancer screenings, and detection of new comorbidities using items from the Follow-Up Care Use Among Survivors (FOCUS) survey developed by NCI and the surveys used in the Childhood Cancer Survivor Study. For example, participants indicate if they received a written/electronic treatment summary or survivorship care plan (SCP; yes/no/don't know). Cancer diagnosis and date of diagnosis will be provided by the NJSCR or the LACSP and confirmed by self-report/during medical record abstraction. Participants' SCP and/or detailed cancer treatment history will be obtained from the cancer center where they were originally treated. This information will be used to rate the intensity of their cancer treatment using the Intensity of Treatment Rating Scale-324 and to determine their personal recommended long-term follow-up care using the most recent Children's Oncology Group Long-Term Follow-Up Care Guidelines (http://www.survivorshipguidelines.org). When not possible to obtain detailed history, registry data will be used to estimate treatment intensity, which has shown to be reliable across most diagnoses, and guide recommendations. Given the purposeful heterogeneity of our sample, we will focus on the most common recommendations. Specifically, we expect all participants to (1) obtain a written/electronic copy of their treatment summary/survivorship care plan and (2) attend a cancer-related follow-up care visit annually. Attendance at a cancer-related follow-up care appointment will be the main focus. The next most common surveillance tests include screening for cardiotoxicity and secondary cancers (echocardiogram, breast exam, pap smear, bone density scan, skin examination). Participants will be deemed adherent if they are up to date on the test per guidelines, which accounts for certain tests being recommended annually while others are recommended every 2-5 years. While our follow-up period of 12 months is too short for some of these tests, those who are nonadherent at baseline are most vulnerable and we would be able to see changes in that group. To account for variation in the number of recommended tests, a proportion score will be calculated for each participant by dividing the total number of recommendations completed by the total number of guideline-recommended tests. Thus, each participant will have a score that could range from 0 to 1, with 0 indicating nonadherent and 1 indicating fully adherent to guideline-concordant care. Co-Investigators Drs. Freyer and Moerdler, both highly familiar with the complexity of medical record documentation, will supervise the coding of these data. (Baseline, 12 months)
Health-related Quality of Life (secondary). The Patient Reported Outcomes

Measurement Information System (PROMIS) Global Health measure is a 10-item measure that assesses self-rated health, physical quality of life, mental quality of life, fatigue, pain, and participation in social activities and roles. The PROMIS measures have undergone extensive testing and are widely used. The Global Health measure yields a Physical Summary and Mental Health Summary scores, in addition to the total score. We will use the total score, which is standardized as a T-score with a mean of 50 and standard deviation of 10. (Baseline, 3 months, 12 months).
Knowledge. The Knowledge subscale of Adult-Oriented Providers subscale from the revised Transition Readiness Inventory will measure survivors' knowledge of survivorship care and transitioning to adult-oriented healthcare. Participants respond to items using a 5-point scale of understanding, from 1 (not at all) to 5 (completely). A total mean score will be used. (Baseline, 3 months, 12 months).
Transition Readiness. The Delegation of tasks, Transition communication, Adult care expectations, and Motivation/Readiness to transition subscales from the revised Transition Readiness Inventory will measure additional theoretically-informed aspects of transition readiness. survivors' knowledge of survivorship care and transitioning to adult-oriented healthcare. Participants respond to items using a 5-point scale of understanding, from 1 (not at all/definitely not) to 5 (completely/definitely yes). A total mean score will be used for each scale. (Baseline, 3 months, 12 months).
Healthcare Self-Efficacy. Healthcare self-efficacy is measured in four domains: late effects, survivorship care planning, health insurance, and communication with healthcare providers. The first three scales have demonstrated adequate internal validity and response to an intervention in prior work and in our pilot feasibility trial. Respondents indicate their degree of confidence using a 5-point likert scale; each scale yields a mean total score, with higher scores indicating higher self-efficacy. The communication self-efficacy is from the Stanford Chronic Disease Self-Efficacy scale and participants rate their confidence communicating with providers on a 10-point likert scale. A total score is used, with higher scores indicating greater self-efficacy. (Baseline, 3 months, 12 months).
Self-regulation of Emotions. The PROMIS Self-Efficacy for Managing Chronic Conditions - Managing Emotions Short Form 8a will measure self-regulation of emotions in the context of illness. It yields a total T-score (standardized to a mean of 50 and standard deviation of 10). Higher scores indicate greater self-regulation. (Baseline, 3 months, 12 months).
Perceived Social Support. The PROMIS Emotional and Informational Support Short- Forms will be used to measure perceived social support. Each measure yields a total score as a T-score, which is standardized to a mean of 50 and standard deviation of 10. Higher scores indicate higher perceived support. (Baseline, 3 months, 12 months).
Barriers to care. Reasons for delaying or forgoing needed medical care will be assessed via a single item (yes/no), including indicating the reason(s) for doing so (e.g., couldn't get the appointment, no transportation, costs too much). Distance from cancer center will be assessed via a single item asking how far respondents live from the cancer center where they received most of their care (<30 minutes, 30-60 minutes, 61-90 minutes, >90 minutes).
Lifestyle health behaviors (including physical activity, alcohol use, tobacco use, and substance use) will be measured using items from published scales.
Internalized shame regarding cancer history will be measured with 2 items,

"I do not feel I can be open with others about my cancer history" and "I feel I need to keep my cancer history a secret," with response options from 1 (strongly disagree) to 4 (strongly agree). Items were adapted to be specific to the context of cancer. A total mean score will be used, with higher scores indicating higher levels of shame. (Baseline, 12 months)

Health Literacy. The Brief Health Literacy Screener is a validated 3-item screener of health literacy assessing the frequency with which participants need help reading medical materials, confidence in filling out medical forms on their own, and difficulty learning about their condition from written information. It yields a total score that can be labeled as inadequate, marginal, or adequate health literacy. We will dichotomize as high/low. (Baseline, 3 months, 12 months).

Financial Hardship. Financial hardship has three domains: material conditions (e.g., medical debt, trouble paying bills), psychological concerns (e.g., worry about paying medical bills), and coping behaviors (e.g., forgoing medical care due to cost). There is no preferred measure for financial hardship for YA-CCS; we use 4 items from the Cancer Self-Administered Questionnaire (CSAQ) that address cancer-related problems, including borrowing money or going into debt, making financial sacrifices, worrying about paying medical bills, or being unable to cover the cost of medical care. Each item is indicated as yes or no, which can be summarized (yes/no) for analysis. (Baseline, 12 months).

Familism and Fatalism. Cultural values may be associated with self-management behaviors and adherence to survivorship care. Familism, the concept of respect and interdependence among family networks, will be measured using a 4-item scale. Items are rated on a response scale from 1 (definitely not) to 4 (definitely yes). An overall mean score is calculated, with higher scores indicating higher familism. Fatalism, the concept that life outcomes are pre-set with little individual control, will be measured using a previously adapted 4-item scale.40,41 Items are rated on a response scale from 1 (definitely not) to 4 (definitely yes). An overall mean score is calculated, with higher scores indicating higher fatalism.

Acculturation. The Acculturation, Habits, and Interests Multicultural Scale for Adolescents (AHIMSA) is a brief multicultural measure applicable to different ethnic groups. Participants respond to each item regarding with preference towards "the United States," "The country my family is from," "Both;" or "Neither." The AHIMSA scale generates four scores based on the four orientations: Assimilation (the total number of "United States" responses), Separation (the total number of "The country my family is from" responses), Integration (the total number of "Both" responses), and Marginalization (the total number of "Neither" responses). The score for each orientation can range from 0 through 8. Factor analysis demonstrated a single factor, so a total score can also be calculated.

Demographics. Participants will report age, sex, race, ethnicity, school/work status, health insurance coverage/stability, marital status, income, and distance living from cancer treatment center. Potentially time-varying characteristics (school/work, insurance, income) will be repeatedly assessed at follow-up surveys.

Peer Mentor-Mentee Relationship Factors:

Working Alliance Inventory – Short Form, Relationship bond, task and goals will be evaluated by mentors' and mentees' report on their perceived alliance using the Working Alliance Inventory – Short Form, a validated measure of

the quality and strength of the relationship that yields a total score. (3 months).
Supportive Accountability. The Supportive Accountability Index is a 6-item measure designed to assess the role of the supportive accountability coach (i.e., the peer mentor) in a digital intervention. The measure demonstrated adequate internal reliability in initial validation and yields a Total Score, which was found to be moderately correlated with engagement with the digital intervention. (3 months).
Perceived experiential similarity. Perceived experiential similarity is measured by two Likert-type items asking participants to rate the extent to which they feel the mentor's cancer experience and general life experiences are similar to their own, using a 7-point rating scale from 1 (very different) to 7 (very similar). A total summary score is calculated. These items were created for use during our feasibility trial. (Baseline, 3 months).
Internal Tracking (completed by research team)
Eligibility Checklist: This checklist will verify eligibility and document reasons for non-participation.
Participant Progress Tracking: The Research Assistant at each site will be responsible for registering and tracking all participants at their site using REDCap, a HIPAA-compliant cloud-based software used for participant tracking, study flow, and administration of participant surveys. Each relying site will only have access to their own participant tracking data to maintain confidentiality. Relying sites may use site-approved software for tracking recruitment strategies; all consented participants will be tracked in Rutgers REDCap. REDCap automates study workflow to remind Research Assistants of upcoming or overdue study tasks (such as tracking of session and survey completion) and can directly email/text participants links to complete surveys and reminders according to the study schedule. This system also tracks participant incentives. It also produces study flow charts to monitor recruitment and retention throughout the study.
Treatment Integrity. Audio recordings of sessions and messages exchanged will be used for weekly supervision with the PI or trained research staff. They may also be used to analyze the content of mentor-mentee discussions. Additionally, 20% of interactions will be randomly selected for treatment fidelity checklist review. The reviewer will listen to the selected session audio recording and complete a structured checklist specific to the manualized content of each session (separate checklists for each call). Items rate the quality of mentor-participant bond (e.g., "mentor and participant clearly engaged, with good rapport, working together throughout session"), communication (e.g., "mentor uses a variety of active listening techniques"), and fidelity to the peer mentor manual (e.g., "mentor reviews participants self-management strengths/weaknesses").
Usability/Engagement with Managing Your Health intervention. Messages exchanged and the time and duration of each call will be archived to monitor engagement. Within the app, each module contains 1-2 items assessing perceived impact of the module. At 3-months, participants will complete select items from the Mobile Application Rating Scale: user version (uMARS), which has been validated to assess the quality of mHealth apps.38 The uMARS yields a total app quality mean score, as well as subjective quality and perceived impact ratings on the user's knowledge, attitudes, and intentions related to survivorship self-management (as items are tailored to the specific app). Participants will also complete the System Usability Scale

(SUS), a standardized scale of perceived usability. Respondents rate each item on a scale from 1 (strongly disagree) to 5 (strongly agree). Raw item scores are adjusted, summed, and multiplied by 2.5 to create a total standardized SUS score, which can range from 0 to 100, with higher scores indicating higher perceived usability. Objective user data (i.e., log-ins, session duration, modules completed, and use of interactive components) will be obtained unobtrusively using MATOMO analytics.

Subject Identifiers:
We will collect participant name, address, telephone number, and email address for contact purposes throughout the study. For eligibility screening purposes, cancer diagnosis and date of diagnosis will be provided by the NJSCR or the LACSP and confirmed during the medical record abstraction. Participants' SCP and/or detailed cancer treatment history will be obtained from the cancer center where they were originally treated. This data will be used to rate the intensity of their cancer treatment using the Intensity of Treatment Rating Scale-324 and to determine their personal recommended long-term follow-up care using the most recent Children's Oncology Group Long-Term Follow-Up Care Guidelines (http://www.survivorshipguidelines.org). Each participant will be assigned a participant ID number and we will keep a key linking the ID number to name for up to 6 years after the close of the study. We will collect MRN, date of birth, and date of diagnosis to abstract medical treatment data from records provided with permission of participants. We will calculate age and time since diagnosis/end of treatment. At the conclusion of the study, identifiers will be removed from the database and de-identified data kept indefinitely.

5.2. Secondary Data Collection

Type of Records:
After obtaining Medical Record Release form from the participant, we will request medical record data from the cancer center they were treated and other primary care/cancer follow-up healthcare provider(s) they see. Please see the attachment "Medical Record Abstraction Variable Request 20NOV2023.xlsx" in DATABASE DETAILS for a list of requested data elements. This list may be amended (and submitted to CPHS for approval via amendment) before we begin recruitment.

Location:
Participant's providers or their designees will send medical records via secure fax or secure email to the research team. We will store them in secure data storage location (e.g., USC OneDrive, site-specific secure location) and abstract relevant de-identified data into the research database.

Inclusion/Exclusion:
We will review the records for all participants on study who sign the medical record release form.

Data Abstraction Form(s):
Data from medical records will be collected such as: written/electronic copy of treatment summary/survivorship care plan including treatment exposures and healthcare utilization including any cancer-related care visit. In addition,

we will collect the date(s) of surveillance tests/orders that include screening for cardiotoxicity and secondary cancers (e.g., echocardiogram, breast exam, pap smear, bone density scan, skin examination), if available. Dates are necessary to determine the degree of adherence to recommended survivorship care.

6. Project Management
The PI and research staff at each site will have the appropriate qualifications and training to conduct the study at each site.

6.1. Research Staff and Qualifications

USC Site PI:
Kimberly Miller, PhD, MPH (Site PI, USC) is an Associate Professor in the Department of Population and Public Health Sciences at USC with expertise in healthcare engagement, utilization, and models of care among young adult cancer survivors. She has a strong research track record, including several R01 cancer registry studies and has prior experience as a research project manager on large-scale national studies. She is well-suited to serve as site PI for the proposed research. At USC, Dr. Miller will be responsible for overseeing all aspects of the study being conducted at USC, including obtaining regulatory approval; training and supervising study staff; facilitating recruitment of study participants; data management; and coordinating with the overall study PI, Dr. Katie Devine (PhD, MPH, Rutgers Cancer Institute).

Overall Study PI:
Katie Devine, PhD, MPH, is the overall study PI. She is a clinical psychologist with expertise in YA-CCS survivorship and transition, including developing the intervention to be tested in this proposal. She will oversee all aspects of the study. This includes coordinating with Site PIs to ensure regulatory compliance, adequate subject enrollment, intervention implementation, and data management across all sites. At the Rutgers Cancer Institute coordinating center, Dr. Devine will be responsible for obtaining Institutional Review Board approval; training and supervising study staff; training and supervising peer mentors; facilitating recruitment of study participants; data management. In addition, she will be responsible for reporting the study's findings.

Peer Mentors: Over the course of the study, we will hire up to 25 peer mentors at each site to serve as mentors in the intervention. Peer mentors will be recruited as paid staff at both sites using healthcare provider referrals and advertisements in the local clinic. Peer mentors for USC participants will be recruited from Children's Hospital Los Angeles, an affiliate of USC. Peer mentor eligibility is (1) diagnosed with any malignant childhood cancer between the ages of 0 and 19 years at least 5 years prior; (2) current age 21-29 years, (3) at least 2 years from treatment, and (4) actively engaged in survivorship care. Following guidelines from the National Mentoring Research Center, potential mentors will complete an application with at least two non-family references. The PI or study staff will interview candidates to assess interpersonal communication skills, level of commitment, and related experience. This approach was successfully used in the two preliminary

feasibility trials. Each mentor will be assigned 2-3 mentees each, typically one at a time to account for busy schedules.

6.2. Research Staff Training
All staff is trained and compliant with CITI requirements to conduct research. Additionally, all staff will attend study start-up meetings to review the protocol, become familiar with study procedures and the proper conduct of the protocol.

Peer mentors at both sites, who are lay community members, will additionally complete the Rutgers Community Involvement in Research Training (CIRTification) program. Peer mentors will attend a half-day training workshop conducted by the PI and study staff (similar to other peer mentor programs). The training will be held either hybrid or fully remote via Zoom, depending on mentor preference. We will hold sessions separately for mentors in NJ and CA for ease of scheduling. Peer mentors will be given the Peer Mentor Handbook, a manual detailing their roles, responsibilities, and the outline for each mentor call (developed in preliminary work). Presentations, interactive discussions, and role plays are used to teach mentors how to provide informational and emotional support to their mentees. Ethical issues, including confidentiality and setting boundaries with peers, are discussed. Peer mentors will have regular weekly supervision with the site PI or study staff once assigned mentees. Peer mentors will be compensated $25/hour for their work.

6.3. Other Resources
Research team members will have access to Rutgers Microsoft OneDrive for secure sharing and storage of documents used at both sites. REDCap software will be used to securely manage participants and collect data at USC.

Participants will be provided with a list of available psychological and social support services if needed.

6.4. Research Sites
Participant and Mentor recruitment will take place at:

1. Rutgers Cancer Institute of New Jersey (Primary), 195 Little Albany Street, New Brunswick, NJ 08903
2. University of Southern California, 3720 S. Flower Street, Los Angeles, CA 90089

IRB reliance agreements will be obtained and uploaded prior to engaging in research.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

Rutgers eIRB_ IRB Approval Issued for Study # Pro2023000838 by Katie Devine.pdf	External IRB Approvals

SRB_Admin_Review approval 132305.pdf	External IRB Approvals
Module1_UnderstandingYourSCP_1.13.22.docx	Instruments
Module2_TakingCharge_1.13.22.docx	Instruments
Module3_ThoughtsAndFeelings_1.13.22.docx	Instruments
Module4_GettingSupport_1.13.22.docx	Instruments
Module5_Staying Healthy in the Context of Life Transitions_1.13.22.docx	Instruments
MYH Module List Table.docx	Instruments
MYH IRB Devine - Response to Reviewer Contingencies 21DEC2023.docx	Other Documents
MYH USC Patient Contact Procedures_revised_02.06.2024_tracked.docx	Protocol

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RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).
Participants will be asked to give permission to audio record the intervention sessions for evaluation of treatment integrity and supervision of the peer mentors. As part of the consent process, participants will be told that it is completely voluntary to agree to the recording and they can change their mind at any time. Peer mentors will be trained to also ask the participant if it is okay to record at the beginning of each session, and to avoid mentioning the participant's name during the recording. Peer mentors will also be instructed to ask participants to avoid stating their name or disclosing PII during the recording. If participants elect to meet with their mentor via videoconference software, only the audio will be recorded (no video recording will occur). It will not be considered a protocol violation if technical issues prevent or disrupt the recording or a trainer forgets to record a session. Digital recordings will be saved on secure local computers at USC and transferred to the main site as soon as possible following each session to the study folder on a cloud-based file storage application for a secure storage, management and sharing of digital files (e.g., Rutgers OneDrive, site-specific platform) and then erased from other means it was recorded to. If PII disclosure should happen during the recording, it will be destroyed or redacted in the file. Recording will be labeled with a subject number rather than any identifiable information. Session audio recording files may be securely transferred between the members of the research team using a site-specific secure file transfer methods.

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

Choose the department(s) from which you are requesting data and/or specimens and provide the formal name of the database or specimen registry. After you have selected the department from the drop down and entered the formal name of the database or specimen registry, click 'add' and repeat to add additional data and/or specimens if applicable.

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	Los Angeles County Cancer Surveillance Program

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

Inclusion criteria:
YA-CCS survivors will be recruited through the New Jersey State Cancer Registry (NJSCR) and the Los Angeles Cancer Surveillance Program (LACSP). Both will follow their standard operating procedures for participant contact, querying the registries to create an initial pool of participants meeting eligibility criteria.

Inclusion Criteria
Participant eligibility includes:
1. Diagnosis with any malignant childhood cancer (ICCC site recode ICD-O-3/WHO 2008) between the ages 0-19 at least 5 years prior
2. Date of diagnosis between July 1999 and July 2019
3. Microscopically confirmed cancer
4. Cancer treatment occurred at a pediatric center/facility
5. Current age on July 1, 2024 between 18-25 (i.e., date of birth July 1, 1999 through July 1, 2006)
6. At least 2 years from treatment completion (typical time for transfer to long-term follow-up care)

Exclusion Criteria
Participant exclusion criteria includes:
1. Any documented physical or self-reported cognitive delay that could prevent self-management of health care
2. Diagnoses of cancer not typically considered pediatric (I.e., melanoma, carcinoma of the breast, colorectum, lung, ovary, and testicle)
3. Unable to speak/read English

Privacy Protections
Initial identification of potential participants will follow registry standard operating procedures. Trained research team members will call participants from a private space, confirm with the subject that they are in a private space for discussion, and offer to reschedule the call if the subject states they are not in the private space.

Number of Subjects
Total number of subjects to be enrolled (Consent+baseline) is 300 across all sites combined. California cancer cases will be N=150.

Feasibility
We expect the recruitment to be completed in 2 years, with approximately 6 to 7 participants recruited monthly per site. We will recruit study participants through the NJSCR and the LACSP. At the time of this application, queries of the NJ and LA registries indicated potential eligible pool of 2,143 and 2,247

respectively, providing ample pool to enroll 300. In our prior feasibility trial, we recruited 50 participants in six months (~8 per month).

DATABASE DETAILS

List the database(s) to be used and the time period(s) being requested. This may include requests for future data that is not available at this time.

List the variables being requested, including a brief description of each variable.
Justify the need for each variable and for the quantity of data being requested.
You may also attach a list of variables on the next question.

Also address if participants will be involved in any other studies.

Los Angeles County cancer participants will be N=150. We will request data on all eligible cases (see inclusion/exclusion criteria in Population Description above) from the Los Angeles County Cancer Surveillance Program. We have attached a list of the variables we will request and a statement of justification.

If you have a list of variables with the details requested in the above question, attach that here. If you provided all details on the database in the question above, skip this question.

Medical Record Abstraction Variable Request 20NOV2023.xlsx	List of Variables
MYH_CCR_DataDict_RequestedVars_071222_30AUG2023.xlsx	List of Variables

RATIONALE

What is the rationale for studying the requested group(s) of participants?

This is a study to assess the efficacy of an intervention (Managing Your Health) aimed to improve self-management of survivorship care among young adult survivors of childhood cancer. Childhood cancer survivors are at risk for adverse late health effects from treatment, including cardiovascular disease, neurocognitive problems, and mental health conditions, with 67-99.9% of adult survivors developing such conditions. Even within the context of high burden of chronic disease, there are racial and ethnic disparities in health outcomes, with a growing body of work suggesting that Hispanic/Latino survivors are more likely to experience poorer health outcomes. Survivors require lifelong "risk-based" follow-up care based on the treatment they received to identify and treat late health effects. Unfortunately, less than 1 in 5 adult survivors of childhood cancer obtain risk-based follow-up care,4 and survivors who identify as Hispanic are less likely to do so. The transition from pediatric to adult follow-up care is a critical period when many survivors are lost to follow-up. This transition involves moving from parent-guided management to self-management of long-term follow-up care, as survivors assume primary responsibility for tasks such as managing health records, making appointments, understanding late effects, and adhering to recommended screenings.

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)?

Important to remember: subjects cannot be contacted before IRB approval.

Method to Identify Potential Subjects
YA-CCS survivors will be recruited through the New Jersey State Cancer Registry (NJSCR) and the Los Angeles Cancer Surveillance Program (CSP). Both will follow their standard operating procedures for participant contact, querying the registries to create an initial pool of participants meeting eligibility criteria. We have identified more than 2,000 YA-CCS who may be eligible in LA County. To obtain our N=150 (per site), we will randomly sample cases from this 2,000 until we achieve our N=150.
Recruitment Details
At USC, study staff will mail an introductory letter and flyer along with CCR brochures to potential participants. Contact tracing is used for those whose mailing address or phone number is not accurate. Because of the age group and possibility of speaking to parents, recruitment scripts include language to inform parents of the research opportunity and request current contact information for their young adult child.

Once introductory letters have been sent, study staff will then be charged with contacting potential participants directly including phone calls, texts, or emails.

A detailed outline of our patient contact procedures is attached (MYH USC Patient Contact Procedures_revised11.29.23.docx).

Subject Screening
Participant eligibility includes (1) Diagnosis with any malignant childhood cancer (ICCC site recode ICD-O-3/WHO 2008) between the ages 0-19 at least 5 years prior, (2) Date of diagnosis between July 1999 and July 2019, (3) Microscopically confirmed cancer, (4) Cancer treatment occurred at a pediatric center/facility, (5) Current age 18-25, and (6) At least 2 years from treatment completion (typical time for transfer to long-term follow-up care).

Participant exclusion criteria includes: (1) Any documented physical or self-reported cognitive delay that could prevent self-management of health care, (2) Diagnoses of cancer not typically considered pediatric (I.e., melanoma, carcinoma of the breast, colorectum, lung, ovary, and testicle), or (3) Unable to speak/read English.

Once staff reach participants, they will administer an Eligibility Checklist (see uploaded document) to confirm eligibility for study participant.

Privacy Protections
Initial identification of potential participants will follow registry standard operating procedures. Trained research team members will call participants from a private space, confirm with the subject that they are in a private space for discussion, and offer to reschedule the call if the subject states they are not in the private space.

Consent Process

Location of Consent Process
Study staff will contact the initial pool of eligible survivors to confirm their eligibility. If individuals are confirmed to be eligible and are interested in participating, study staff will then discuss consent via telephone.

Ongoing Consent
Survey instructions will include a reminder of the voluntary nature of participation. All email communications with participants will include study staff contact information and encourage participants to contact the PI or study staff with any questions.

Individual Roles for Researchers Involved in Consent
The site PI, project coordinator, or trained research staff member will obtain consent.

Consent Discussion Duration
We expect most initial consent discussions to take approximately 10 minutes.

Coercion or Undue Influence
The consent process will emphasize that participation is voluntary.

Subject Understanding
The site PI or trained research team member obtaining consent will encourage questions and ask the participant to state in their own words their understanding of the research study, including risks, benefits, and voluntary nature of participation.

Protecting Privacy
Initial identification of potential participants will follow registry standard operating procedures. Trained research team members will call participants from a private space, confirm with the subject that they are in a private space for discussion, and offer to reschedule the call if the subject states they are not in the private space.

Attach copies of all recruitment materials.

CCR Patient Information Brochure English.pdf	Recruitment Materials
Communication msgs to Participants V3_01.29.2025_tracked.docx	Recruitment Materials
CPHS Bill of Rights Non Med.pdf	Recruitment Materials

Digital Self-Management Phone Consent Script_USC_22NOV2023_New.docx	Recruitment Materials
Digital Self-Management_Eligibility check_USC 4_01.29.2025_tracked.docx	Recruitment Materials
Digital Self-Management_Letter with MedRecords release form_USC_21NOV2023.docx	Recruitment Materials
Digital Self-Management_Patient letter_USC_22NOV2023_tracked.docx	Recruitment Materials
Digital Self-Management_Recruitment scripts_USC_29NOV2023_tracked.docx	Recruitment Materials
Measure_uMARS Mobile application rating scale mhealth_v4i2e72_app1.pdf	Recruitment Materials
MedReleaseForm_online_revised 112023 USC.docx	Recruitment Materials
MYH Informed Consent USC_v3_01.30.2025_tracked.docx	Recruitment Materials
MYH USC Patient Contact Procedures_revised_02.06.2024_tracked.docx	Recruitment Materials
ParticipantCommunication_UpdateMedRelease_11.17.23.docx	Recruitment Materials
Survey Measures T1 T2 T3 Combined_01.29.2025_tracked.docx	Recruitment Materials
Survey Measures T1_02.07.2025_tracked.docx	Recruitment Materials
Survey Measures T2_02.07.2025_tracked.docx	Recruitment Materials
Survey Measures T3_02.07.2025_tracked.docx	Recruitment Materials
USC_Flyer Recruitment_Digital SelfManagement_9.23.2024.pdf	Recruitment Materials
Website layout pdf_12.1.2024Clean.pdf	Recruitment Materials

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SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
Study staff will contact the initial pool of eligible survivors by telephone to confirm their eligibility. Study staff will ask participants to confirm the following:

Their date of birth, which must be consistent with a current age of 18-25 years old.
The month and year they were diagnosed with cancer.
The month and year they completed cancer treatment, which must be at least 2 years prior.
Who is primarily responsible for their health care, which must not be managed independently.
Their responses to the Readiness Transition Questionnaire, which must have at least 2 of 10 scores of less than 3.
Their response to the question, "Overall, how ready do you think you are to assume complete responsibility for your health care?", which must be either 'Not at All' or 'Somewhat'.

Please refer to the Eligibility Check document provided in the RECRUITMENT DETAILS section of this application for more details (Digital Self-Management_Eligibility check USC 22NOV2023_tracked.docx).

We are not recruiting any vulnerable populations.

Responses to the eligibility questionnaire are used for eligibility determination. Responses will be collected anonymously (without any names or PII), will be stored separately from study data, and will reported in aggregate (i.e., not connected to any individual) in the final reports/manuscripts related to this study. We will retain only the age of the individual, rather than their date of birth, to further ensure anonymity.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
This is a five-year study in which each participant will participate for one-year. Participants will be surveyed 3 times over this one year of participation. Participants will receive a $50 electronic gift card for each completed survey, for a total of up to $150. Research staff will maintain documentation of compensation by maintaining a list of disbursed gift cards and copies of electronic communications indicating the gift card was sent.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

The overall study will last 5 years, and we expect the recruitment to be completed in 2 years. Each subject will participate for 1 year.

Each subject will be contacted by study staff to discuss consent. We expect most initial consent discussions to take approximately 10 minutes.

Surveys will be administered at baseline, 3 months (post-intervention), and 12 months (9-month follow-up). We anticipate each survey will take approximately 25 minutes.

The initial consent conversation plus each survey will total to an approximate total time commitment of 1 hour and 25 minutes over the year-long participation period for each subject.

Additionally, the intervention group will spend approximately 6 hours over the course of the 6-week intervention period engaged in the peer mentoring curriculum. The control group will be provided materials that are roughly the equivalent amount of time. Thus, total participation time for all participants will be approximately 7 hours and 25 minutes.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

Potential risks are considered minimal and include breach of confidentiality. There are no physical risks associated with participating. It is possible that participants may feel psychological or social discomfort when interacting with peer mentors. Although psychological discomfort related to survey questions is unlikely, participants may choose not to answer any question and may withdraw at any time.

Risk of Harm from an Intervention on a Subject with an Existing Condition
All participants will be childhood cancer survivors and the intervention is targeted to address the needs of these individuals.

Other Foreseeable Risks of Harm
A possible loss of confidentiality could cause embarrassment for a participant but is unlikely to cause any social harm or consequences given no collection of sensitive data.

Assessment of Social Behavior Considerations
We focus our monitoring on any distress that may arise from research activities rather than any general underlying distress experienced by this population. Therefore, we will monitor for any research-related distress through a brief distress screener anchored to the emotion management module. Anyone who screens high will be contacted by research staff to assess distress, safety, and provide referrals if needed. Peer mentors are trained to respond to general participant distress if it occurs at any time during the study, including a script with resources to provide to participants (such as cancer help lines and counseling services). Supervisors will routinely ask about any instances of participant distress during weekly mentor supervision. As part of the informed consent process, participants are also given information about how to access appropriate resources if distressed.

Minimizing Risks of Harm
Several strategies will be implemented to minimize risk to research participants. Peer mentors will be rigorously trained and supervised. All data will be kept confidential; names of participants will not appear in the research database (participants will be identified via subject numbers). The data file linking names and the unique subject numbers will be accessible only to the PI and project staff who require access for participant tracking and retention purposes. Digital audio files from the intervention sessions will be stored on the secure Rutgers OneDrive with restricted access (i.e., access granted only to study team members who require access). All participants will be informed that their participation is voluntary and they may withdraw at any time without consequences. They will also be informed of whom they

may contact if they have questions about their rights as participants or questions about the research. Online surveys will be completed by participants using a secure website hosted on REDCap servers. For medical record transfer, we will request transfer via cancer registry-approved secure fax or secure/encrypted email. Confidentiality will be further maintained by reporting only group data in study publications and presentations.

Certificate of Confidentiality
This study is NIH-funded, for which a Certificate of Confidentiality is automatically issued to protect the data obtained.

Provisions to Protect the Privacy Interests of Subjects
Participants will only be contacted by trained and authorized research staff. The consent process will detail expected interactions and data use.

AUDIO/VIDEO RECORDING RISKS

State if audio/video taking could increase potential risk to subject's confidentiality.

Audio could increase potential risk to subject's confidentiality. To avoid capturing PII on the audio recordings, peer mentors will be trained to avoid mentioning the participant's name during the recording. Peer mentors will also be trained to ask participants to avoid stating their name or disclosing PII during the recording. If PII disclosure should happen during the recording, it will be destroyed or redacted in the file. Digital recordings will be transferred to the main site as soon as possible following each session to the study folder on a cloud-based file storage application for a secure storage, management and sharing of digital files (e.g., Rutgers HIPAA-Compliant OneDrive, site-specific platform) and then erased from other means it was recorded to. Recording will be labeled with a subject number rather than any identifiable information. Session audio recording files may be securely transferred between the members of the research team using site-specific secure file transfer methods (e.g., Rutgers HIPAA-Compliant OneDrive file sharing feature).

Note: If participants elect to meet with their mentor via videoconference software, only the audio will be recorded (no video recording will occur).

MEDICAL SERVICE RISKS

Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided, state that clearly.

No medical services will be provided if subjects suffer adverse or physical effects as a result of our research activity. This research is minimal risk.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

There are no less risky methods to be used.

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

Participants may benefit by enhancing their self-management behaviors, resulting in improved health-related quality of life and better adherence to guideline-concordant care. However, there may be no direct benefit from taking part in the study. The minimal risk involved in this study is reasonable in relation to the anticipated benefits of the research.

JUSTIFICATION OF RISKS

Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

The potential benefits to humanity justify exposure of the participants to the risks.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
Telephone numbers
Email address
Social Security Number
Medical record number

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

All information and data collected as part of this research will be accessible only to research staff who have completed the mandatory CITI training in the protection of human subjects, HIPAA training, and training in Los Angeles County Cancer Surveillance Program cancer surveillance confidentiality and security procedures. All staff will receive this training in which Dr. Miller will also participate.

STAFF VETTING PROCEDURES

Describe procedures, either background check or thorough reference check, for vetting staff who will have access to PID.

All staff (including peer mentors) are trained and compliant with CITI requirements (including CITI's HIPAA training) to conduct research. All staff working with LACSP registry data will be required to complete the required LACSP annual training module. Additionally, all staff will attend study start-up meetings to review the protocol, become familiar with study procedures and the proper conduct of the protocol.

Additionally, peer mentors, who are lay community members, will complete the Rutgers Community Involvement in Research Training (CIRTification) program. Peer mentors will attend a half-day training workshop conducted by the PI and study staff. The training will be held either hybrid or fully remote via Zoom, depending on mentor preference. We will hold sessions separately for mentors in NJ and CA for ease of scheduling. Peer mentors will be given the Peer Mentor Handbook, a manual detailing their roles, responsibilities, and the outline for each mentor call (developed in preliminary work). Presentations, interactive discussions, and role plays are used to teach mentors how to provide informational and emotional support to their mentees. Ethical issues, including confidentiality and setting boundaries with peers, are discussed. In the feasibility trial, peer mentors reported high satisfaction with this training (M = 3.85, SD = 0.32 on 1 to 4 rating scale). Peer mentors will have regular weekly supervision with the site PI or study staff once assigned mentees. Peer mentors will be compensated $25/hour for their time and effort.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

SIGNED_CPHS_LOS_Miller, K.pdf Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Only authorized study personnel will have access to study data, and access to identifiable data will be limited to staff who need the data to interact with participants. Survey and medical record data will be stored in a separate database from identifiable data (e.g., name, address, etc.). The link between subject name and ID will be destroyed 6 years after the close of the study; other study data will be kept indefinitely. All computers used for research purposes adhere to the institution’s requirements regarding password protection, data encryption, anti-virus protection, and intrusion detection. All Internet-based data communications will be encrypted. Physical records will be stored in a locked filing cabinet with the PI’s locked office at each site.

Study staff are given access to the folder via individual username and passphrase and receive annual training on confidentiality, specifically on issues surrounding the appropriate use of data, and non-disclosure and non-reuse. This training is conducted by the Los Angeles County Cancer Surveillance Program and meets California Cancer Registry requirements.

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

Any publications and presentations related to this work will contain only aggregate data and conclusions drawn from studying the data. No data that will be published could possibly be used to identify an individual subject. All data published will be de-identified.

Individual Subjects' Results
N/A – results will be calculated on the aggregate data; no relevant data for sharing with subjects.

Aggregate Results
We will post aggregate results on clinicaltrials.gov for public viewing.

Professional Reporting
It is expected that the results of this research will be submitted for publication in a timely manner following the conclusion of the study. The PI and all co-authors will review any abstract or manuscript prior to submission.

Clinical Trials Registration, Results Reporting and Consent Posting
This trial will be registered at clinicaltrials.gov. Results will be reported and the approved consent form uploaded.

Secondary Use of the Data
We will make de-identified data available for sharing with other qualified researchers for secondary research. This is described in the consent form.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

Registry Data:
The data and dataset requested aligns with the minimum sample size to adequately address the study aims. An initial query identified approximately 2,000 eligible participants, and based on previously enrollment statistics, this makes our sample size of 300 feasible. Since this study is focused on young adult survivors of childhood cancer, we have stipulated that participants must be between the ages of 18-25 and must have had a childhood cancer diagnosis at least 5 years prior and between 0-19 years of age. Additionally, to capture transition of care, participants must have received treatment at a pediatric center/facility. In order to ensure that participants have completed their course of treatment and are likely to be in the transition time to long term follow-up care, we have included an inclusion criteria that participants must be at least 2 years from treatment completion.

Demographic data collected from the registry will be used to assess eligibility and will enable us to address our research objectives. These variables include: age, sex, race, ethnicity, health insurance at diagnosis, and neighborhood socioeconomic status. These variables will be used to assess one of our aims: identify subgroups of participants for which treatment effects vary to inform future scale up.

We will request no more than the minimum necessary data to perform the research.

Questionnaires and intervention:
Study instruments will be concise and specific to answering our research questions and hypotheses. Surveys will include questions on self-management behaviors, adherence to guideline-concordant survivorship care, health-related quality of life, knowledge of survivorship healthcare components, healthcare self-efficacy, self-regulation of emotions, perceived social support, health literacy, financial hardship, and assessment of factors related to peer mentor-mentee relationship functioning. Lastly, data to evaluate internal tracking will be gathered such as participant-specific progress tracking, eligibility checklists, treatment integrity, and usability/engagement with the study intervention.

Since this is a randomized control trial, only those randomized to the intervention group will receive the "Managing Your Health" peer mentoring intervention while those in the control group will receive an SMS message with Health Links developed by the Children's Oncology Group for use in survivorship care. Participants will be randomized by ethnicity and sex (Hispanic and male) to achieve . "Managing Your Health" will be delivered by trained study staff and will involve participation in six weekly video

conference calls with a peer mentor and five self-management educational modules. Surveys will be used to test the feasibility of this intervention and associated outcomes which will address our study aim of determining the mechanism though which managing your health influences outcomes and evaluating the efficacy of the Managing Your Health intervention.

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

Only authorized study personnel will have access to study data, and access to identifiable data will be limited to staff who need the data to interact with participants. All study staff will complete training on data security practices prior to being given access.

UNIQUE IDENTIFIERS

If applicable, justify why unique identifiers, other than social security numbers, cannot be used.

Unique identifiers will be used throughout - SSN is only being requested from LACSP to aid in tracing individuals whose contact details are out of date, and will be destroyed once updated contact details have been obtained.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

All publications from this study will adhere to California Cancer Registry's minimum cell size for
reporting (currently <11 cell sizes are suppressed). There are no linkages to other datasets in this study.

LINKAGES

Will the data set be linked with any other data sets?

No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

CINJ_SecurityLetter_1.18.24-signed.pdf	Data Security Letter
Data Security Letter - Kimberly Miller - Intervention to improve transition from pediatric to adult for childhood cancer.pdf	Data Security Letter

Physical Safeguards

DATA PROTECTION

Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room, desk, or office.

Yes

DATA DESTRUCTION

Will data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will contain personal identifiers

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

PID in paper form will be disposed of through cross cut shredding.

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

For medical record transfer, we will request transfer via cancer registry-approved secure fax at our LA CSP offices at USC. The fax will go to authorized study staff only.

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

The USC site does not anticipate using paper survey mailings in this study to recruit LACSP participants. However, in the unlikely event of significant technical difficulties, paper copies may be mailed to participants with a postage-paid return envelope. All mailings containing PID will be sealed and secured for each individual subject and will be sent using USPS.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

PID on portable electronic storage media will never be left unattended in cars or unsecured
locations. Laptops are never to be left in unsecured locations and always kept locked with a cable at a workstation. Paper materials and storage media (USB drives and CDs) will be also kept in a locked cabinet when not in use.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Any paper forms or surveys containing PID will be stored in a locked file cabinet, separate from any other project data. Signed electronic consent forms will be securely downloaded and stored on the secure Rutgers OneDrive with restricted access (i.e., access granted only to study team members who require access) and will remain separate from study data.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

Online surveys will be completed by participants using a secure website hosted on HIPAA-compliant REDCap servers. For medical record transfer, we will request transfer via secure fax or secure/encrypted email. Confidentiality will be further maintained by reporting only group data in study publications and presentations.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Survey and medical record data will be stored in a separate database from identifiable data (e.g., name, address, etc.). The link between subject name and ID will be destroyed 6 years after the close of the study; other study data will be kept indefinitely.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be properly destroyed.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

All computers used for research purposes adhere to the institution's requirements regarding password protection, data encryption, anti-virus protection, and intrusion detection. All Internet-based data communications will be encrypted. All information collected as part of this research will be accessible only to research staff who have completed mandatory training in the protection of human subjects.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

All workstations will have full disk encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

All laptops that contain PID have full disc encryption that uses FIPS 140-2.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

PID on removable media devices are encrypted with software that is FIPS 140-2 compliant.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

All computers used by the study team are managed by USC or Rutgers's IT services who update software and apply patches in person or remotely as they become available.

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

Strong password controls (minimum 16 character passphrases) are in place to protect PID stored workstation, laptops, servers, and removable media. Passwords are required to be changed at least annually.

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

Security controls are in place for automatic screen timeout, automated audit trails, intrusion
detection, and anti-virus.

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

All transmissions of data are first encrypted, and all connections to the internet require USC's VPN.

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

PID in electronic form will be accessible using the internet to connect to servers - but only with
VPN and dual authentication.

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

When disposing of electronic PID, physical destruction will be used as well as secure wiping (done by trained IT study personnel).

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Researchers must disclose any COI, including perceived COI.

Financial relationships to be disclosed include but are not limited to the following:

- **Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.**
- **Receipt or expectation of payment of any sort in connection with papers, symposia, consulting, editing, etc. from the source of funding.**
- **The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.**
- **Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.**

DISCLOSURES

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

No

Informed Consent Procedures

INFORMED CONSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed consent from participants.

See instructions and examples on CPHS website.

Location of Consent Process
Study staff will contact the initial pool of eligible survivors by telephone to confirm their eligibility. If individuals are confirmed to be eligible and are interested in participating, study staff will then discuss consent. Participants who are interested will be directed to a HIPAA-compliant REDCap site maintained by Rutgers where they will be able to read, sign, and download a copy of the informed consent as well as the patient Bill of Rights. The study staff will offer to stay on the phone and walk them through the consent if preferred, or they may review the consent form on their own time. If they have questions regarding the consent they may contact Ms. Marin and/or the study PI. If they do not want to participate further in the study there will be an option to note that they are not interested.

Details about the consent process and a list of relevant attachments can be found in the attachment "MYH USC Patient Contact Procedures.docx" (see the STUDY PROCEDURES or RECRUITMENT DETAILS section for this attachment).

Ongoing Consent
Survey instructions will include a reminder of the voluntary nature of participation. All email communications with participants will include study staff contact information and encourage participants to contact the PI or study staff with any questions.

Individual Roles for Researchers Involved in Consent
The site PI, project coordinator, or trained research staff member will obtain consent.

Consent Discussion Duration
We expect most initial consent discussions to take approximately 10 minutes.

Coercion or Undue Influence
The consent process will emphasize that participation is voluntary.

Subject Understanding
The site PI or trained research team member obtaining consent will encourage questions and ask the participant to state in their own words their understanding of the research study, including risks, benefits, and voluntary nature of participation.

Protecting Privacy
Initial identification of potential participants will follow registry standard operating procedures. Trained research team members will call participants

from a private space, confirm with the subject that they are in a private space for discussion, and offer to reschedule the call if the subject states they are not in the private space.

CONSENT FORMS

Attach copies of consent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website.

Be sure to include a concise explanation of key information for participants at the beginning of your consent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the same CPHS website). CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, attach a document that explains how all of the criteria below will be satisfied.

CPHS Bill of Rights Non Med.pdf	Consent Form
Digital Self-Management Phone Consent Script_USC_22NOV2023_New.docx	Consent Form
Digital Self-Management_Letter with MedRecords release form_USC_21NOV2023.docx	Consent Form
Digital Self-Management_Recruitment scripts_USC_29NOV2023_tracked.docx	Consent Form
MYH Informed Consent USC_v3_01.30.2025_tracked.docx	Consent Form
ParticipantCommunication_UpdateMedRelease_11.17.23.docx	Consent Form

Deleted Attachments: 1 (Most Recent: MYH Informed Consent USC_v3_01.30.2025_tracked.docx on 02/13/2025 5:51 PM ET)

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

No

HEALTHCARE PROVISIONS

Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

Yes

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

If you have already received a waiver/alteration from another IRB choose 'waiver/alteration approved by another IRB'. You do not need to apply for a waiver or alteration as the HIPAA waiver or alteration of authorization is only required from one IRB.

No

HIPAA AUTHORIZATION FORM

Upload a copy of the HIPAA Authorization form(s) or the documentation of the approval of a waiver/alteration from another IRB.

MedReleaseForm_online_revised 112023 USC.docx HIPAA Documents

Amendment Changes

List the pages and questions that have been changed.

We have changed or added information or files in the following areas:

Pg 2 - Personnel Changes
Ricky Bluthenthal replaces Howard Hu as Responsible Official
Jonathan Kaslander added to Research Team and replaces Laura Thompson as Admin contact (Laura Thompson removed from Research Team)
Scott Moerdler replaces Margaret Masterson as Co-PI

Pg 4 - Changes in sections 1.1 and 5.1

Pg 5 - Documents uploaded
Updated:
Survey Measures T1 T2 T3 (all and individual time periods)
Digital Self-Management_Eligibility check_USC
Communication msgs to Participants
MYH USC Patient Contact Procedures_revised
MYH Informed Consent USC
USC_Flyer Recruitment_Digital SelfManagement
New:
Website layout pdf

Pg 11 - Updated document uploaded
MYH Informed Consent USC

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

budget justification FINAL.pdf	Project Budget
Budget_Miller_Devine 7.21.23.xlsx	Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover letter CPHS.docx	Cover Letter

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.

Calculated Field for agency plus data set *(Internal)*

California Department of Public Health: Los Angeles County Cancer Surveillance Program

PI Signature for Coordination Submission (Amend) - Submitted 02/24/2025 1:09 PM ET by Katie Devine, PhD

PI Review

Please click "Next" and "Submit" in order to submit this application, regardless of whether or not it is ready for review. If you indicated it is ready for review, the amendment will be submitted to the CPHS Office, and if not, it will be returned to the individual who completed the form for changes.

Is this application ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Monday, February 24, 2025 1:09:35 PM ET by Katie Devine, PhD

Notify IRB for Pre-Screening
- Submitted 03/04/2025 3:35 PM ET by Nicholas Zadrozna

Internal IRB Screening

The questions on this page will be blank when an amended copy is submitted. If the form is returned during the amendment review, the questions on this page will appear as answered previously during the amendment review (responses from the initial review will not appear)

Is this study ready to be reviewed by the CPHS panel?

Yes

Choose the IRB committee to review this study (this defaults to CPHS)

CPHS

Level of Review Determination (once the level of review is assigned for this project, do not change this answer unless the reviewer/committee has decided that the study requires a different level of review)

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
The researchers are requesting the following changes to the protocol:

1) change of personnel (new administrative contact, co-PI, and RO)

2) additions and edits to survey measures

3) revisions and edits to participant eligibility screener

4) edits to participant communication

5) edits to Informed Consent Form

6) edits to recruitment flyer

7) addition of participant website

(Ms. Lund requests to have this reviewed during the April full board meeting)

Choose the CPHS Chair
Catherine Hess, PhD

Select the vice chair of the committee
Larry Dickey, MD, MPH, MSW

Assign to Cycle

April

Assign to cycle year
2025

Load into IRBManager (Amendment)
- Submitted 04/08/2025 1:24 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 03/25/2025 7:14 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2023-190

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
This amendment is scheduled to be discussed in the CPHS April 25, 2025, full board meeting at a request received from Ms. Lund (Primary reviewer of the project) because many aspects of this study involving human subjects contact have been significantly modified in this amendment, including questionnaires and the informed consent form.

Assign SME to study

Laura Lund, MA

Enter the meeting date for this project

04/04/2025

SME Review

SME review

After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.

If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.

Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.

Yes

Enter any additional comments that you have for the researcher (in addition to your notes) here.
See comments in IRB Manager

In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.