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

View xForm - Project Application v6

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

Data entry
- Submitted 05/23/2024 4:47 PM ET by Marcie Haydon, PhD

Amendment Header

Amendment Submitter

august 2024 cycle

05/28/2024 • Nicholas Zadrozna • Internal

Marcie Haydon, PhD

Email: mdhaydon@hs.uci.edu **Business:** (949) 924-5281

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:

Michael A Hoyt, PhD

Email: mahoyt@uci.edu **Business:** (949) 824-9937

Administrative Contacts:

Name	Role

Protocol Number:

2020-112

Protocol Title:

A Biobehavioral Intervention for Latino/Hispanic Young Adults with Testicular Cancer

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

Recruitment strategy and/or materials
Research methodology and/or research questions
Additional data sets requested
Population, sample size, inclusion/exclusion criteria
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

Due to infusion of funding, the current study can now be expanded to include young adult male Hispanic/Latino cancer patients of any type, not just testicular cancer as previously approved. Additionally, the additional funds allow us to convert the currently approved single-arm trial to a randomized trial with intervention (GET) and time- and attention-matched control (ISL) groups. Below is a summary of changes made to the consent form: (1) Revised all mentions of testicular cancer to broadly "cancer", (2) Clarification of saliva collection timing, (3) Removal of qualitative interview option (the study team obtained sufficient qualitative data from the initial cohort of participants and will no longer be conducting qualitative interviews with new participants), (4) Revision of sample size from 70 to 170 Latino YA cancer survivors, (5) Removal of treatment time window requirement, (5) Addition of inclusion criteria--diagnosed between the ages of 15-39, (6) Addition of consent to video record along with already approved audio recording, (7) Addition of REDcap to remove Qualtrics, and (8) Addition of a follow-up assessment (at 3-months). We will also be requesting additional data from the California Cancer Registry to facilitate recruitment of this new population.

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)*

Irvine

PI Location State Output *(Internal)*

CA

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
Beverley Alberola, PhD	Responsible Official
Jose Lechuga, MS	Coordinator
Karen Llave, MPH	Coordinator
Marcie Haydon, PhD	Research Team
Michael A Hoyt, PhD	Research Team
Michael A Hoyt, PhD	Principal Investigator

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

*No change in personnel

Project Information

SUBMITTER

Application completed by:

Marcie Haydon, PhD
Email: mdhaydon@hs.uci.edu **Business:** (949) 924-5281

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).

A Biobehavioral Intervention for Latino/Hispanic Young Adults with Cancer

STUDY PROCEDURES

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

Data Registry
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
HIPAA waiver
Consent form
Informed Consent Waiver

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.
University funded

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

08/17/2020

ANTICIPATED PROJECT END DATE

05/31/2025

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.

Cancer can be distressing in the formative period of young adulthood. In fact, the majority of young adult cancer survivors will experience impairing, distressing, and modifiable physical, behavioral, and psychosocial adverse outcomes that persist long after the completion of primary medical treatment. These include psychological distress, impairment in the navigation and pursuit of life goals, persistent side effects, elevated risk of secondary malignancies and chronic illness, and biobehavioral burden (e.g., enhanced inflammation, dysregulated stress hormones) which influence morbidity and disease-related vulnerabilities. However, few targeted, tailored, culturally-relevant interventions exist to assist young Hispanic/Latino survivors in re-negotiating life goals and regulating cancer-related emotions and none focus on reducing the burden of morbidity via biobehavioral mechanisms. Young or "emerging" adulthood is a period marked by goal attainment. Behavioral intervention at this time is well positioned to confer longer-term impact. Emergent from our group's preliminary research, we developed and pilot-tested Goal-focused Emotion-Regulation Therapy (GET) as a novel behavioral intervention to enhance self-regulation through improved goal navigation skills, improved sense of purpose, and better ability to regulate emotional responses in young adults with testicular cancer. GET is a promising candidate intervention to address the mechanisms likely complicating the resolution of cancer-related burden. Responsive the need for feasible and effective interventions that meet the need of ethnic minority men, we will conduct a sequential trial. In Study 1, 70 Hispanic/Latino young adults (ages 18-39) with testicular cancer will receive 6 sessions of GET. We will evaluate primary and secondary outcomes at baseline, post-treatment, and 3-month follow-up. Further, we believe that GET could be optimized to meet the needs of this group. To this end, we will examine the influence of Latino cultural processes (Familism, Machismo/Caballarismo, Simpatia, Acculturative Stress), and conduct in-depth qualitative interviews. Study 2 will share the same outcomes, compensation, and timepoints but will include Hispanic/Latino young adult (ages 18-39) men with cancer (all types) randomized to GET or a time- and attention-matched control (Instrumental Supportive Listening; ISL).

MAJOR RESEARCH QUESTION

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

Study 1 (single-arm trial):

Aim 1: Determine the impact of the GET intervention in improving depressive symptoms (primary outcomes) as well as emotion regulation, goal attainment skills, and career confusion (secondary outcomes) in young adult Hispanic/Latino testicular cancer patients.

Aim 2: Examine the change in salivary markers of distress-relevant biomarkers (e.g., diurnal cortisol) and inflammation (i.e., soluble tumor necrosis factor-alpha receptor II, Interleukin 6) in young adult testicular Hispanic/Latino cancer patients receiving GET.

Aim 3: Identify the influence of culturally relevant influences (i.e., familism, acculturation/acculturative stress, machismo) on the impact of GET for young adult Hispanic/Latino testicular cancer patients.

Exploratory Aim: Evaluate the ability of GET to alter epigenetic vulnerability (DNA methylation) with a focus on NR3C1 (glucocorticoid receptor gene) and SLC6A4 (serotonin transporter gene).

Study 2 (randomized-controlled trail):

Aim 1: Determine the efficacy of GET as compared to Instrumental Supportive Listening (ISL) in improving depressive and anxiety symptoms (primary outcomes) as well as emotion regulation, goal attainment skills, and career confusion (secondary outcomes) in young adult H/L men with cancer.

Aim 2: Examine the relative change in salivary markers of distress-relevant biomarkers (i.e., diurnal cortisol parameters) and inflammation (i.e., Interleukin-1-receptor antagonist, Interleukin-6) in young adult H/L men with cancer receiving GET (vs. ISL).

Aim 3: Identify the moderating influence of culturally-relevant processes (i.e., simpatía, machismo) on the impact of GET (vs. ISL).

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

A primary goal of Study 1 is to determine feasibility and acceptability of the developed intervention for young adult Hispanic/Latino cancer survivors. Study 1 (n = 70) will utilize a non-randomized open trial mixed-methods design among young testicular cancer survivors. Preliminary clinical "signal" will focus on improvements in depressive and anxiety symptoms (primary outcomes) as well as emotion regulation, goal attainment skills, and career confusion (secondary outcomes), and whether GET is associated with reductions in biological markers of stress and inflammation as assessed at baseline (T0), post-intervention (T1), and 3-month follow-up (T2). Acceptability and adaptability will be assessed through the examination of moderation effects of relevant cultural values and factors and the use of in-depth interviews following participation.

Study 2 (n = 100) will assess preliminary efficacy, and will utilize a randomized-controlled design among young Hispanic/Latino survivors of any cancer type. This study will share the same outcomes, compensation, and timepoints but will include Hispanic/Latino young adult (ages 18-39) men with cancer (all types) randomized to GET or a time- and attention-matched control (Instrumental Supportive Listening; ISL).

The intervention will be delivered via an interactive video platform to enhance greater access and inclusion of rural and hard-to-reach survivors. Telephone sessions will also be offered for those with computer accessibility barriers.

Participants will be recruited from outpatient clinics at UCIMC, advertisement to community cancer and health care organizations, and the California Cancer Registry.

All individuals interested in participating will be complete a 12-item screening (~5 min) with two subscales from the CAYA (either in person or over the phone). Participants who score < 1.8 on the goal navigation scale or < 0.6 on the goal facility scale of the CAYA or >4 on the Distress Thermometer will be invited to participate. If individuals decide they are not willing to complete a screening questionnaire, no further follow up will be conducted. As this procedure presents no more than minimal risk to the privacy of the individuals who are screened and only minimal personal information will be maintained as part of the screening log, a (partial) limited waiver of authorization will be sought for the purposes of (1) conversing with patients regarding possible enrollment; and (2) maintaining information in a screening log of patients approached. This is done primarily to ensure that we do not recontact an individual and to maintain a record of reasons for ineligibility, which is required for reporting of clinical trial results.

This is not to acquire PHI, but rather to understand and assess eligibility. Any identifying information recorded during recruitment and screening is maintain separate from any information obtained from screening. Further, all identifying information is destroyed at the close of recruitment.

After consent, the study research assistant will also ask participants to provide us with two emergency contacts and the name, city/state, and/or phone number of a local hospital, as well as contact information for and permission to contact any treating mental health professionals (including anyone prescribing psychotropic medication) and/or a primary care physicians if applicable. Although participation in this study presents no physical and limited psychological risk and we do not anticipate any problems emerging, we want to have these contacts available if we cannot reach a participant or in the case of an emergency. During consent, we will inform participants that emergency contacts will only be contacted in the event that we are concerned about severe distress and/or suicidality. Confirmation that this is understood will be sought during consent, and participants will be informed at this time that at least two emergency contacts, one of whom can be a health provider, will need to be provided in order to participate. After we request emergency contacts, we will ask for the participant's contact information. Contact information collected will include an e-mail address and the participants' communication preferences. For any communication with participants, all security precautions will be taken.

The screening process for the protocol requires administration of screening questionnaires. In following the Code of Federal Regulations Title 45, Part 46, Subpart A, which states that an IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, a signed consent may not be required for this study. In accordance with the aforementioned regulations, we request to waive consent for identifying whether the patient is eligible, which includes administering the pre-screening measures.

If a participant is ineligible for the research study, the research staff will destroy all information collected during the initial eligibility determination, except for any minimal information maintained for screening log purposes (e.g., age, race, ethnicity, outcome of approach, and reasons for ineligibility). We will also maintain a list of all participants approached throughout the entire study to record reasons for refusal and avoid approaching patients multiple times if they have been identified as ineligible or refusers. This list will be destroyed at the completion of the project.

Following the screening, informed consent, and randomization, participants will be asked to complete the baseline assessment which includes psychosocial questionnaire measures (administered online via UCI REDcap platform) and at-home saliva collection/oral swab. These assessments will be completed prior to 1st intervention session. The assessment battery will be re-administered at T2 (post-intervention, following the 6th session of the intervention). Furthermore, at T2 participants will be asked to provide

another set of saliva samples/oral swab, as detailed below. In Study 1, following completion of T2 assessments, participants will be scheduled for a qualitative interview about their experiences in the intervention. Participants (both studies) will then be asked to complete questionnaires and at-home saliva collection at 3-months post-intervention (T3).

Salivary stress markers/Oral swab for inflammation markers: Saliva samples will be collected using individual salivettes. Participants will be mailed salivettes for the pre- and post-intervention and 3-month follow-up assessments along with detailed instructions for saliva collection. They will be instructed to collect saliva 4 times per day for 3 days. On the fourth day, participants will also be asked to collect oral mucosal transudate (OMT) via oral swab. OMT will be collected using the OraSure oral swab. Participants swab for 2 minutes. The swab is removed from the mouth and placed in the vial containing an aqueous antimicrobial preservative solution. An envelope will be provided for direct shipping of the samples back to the PI at UCI address. Participants will be asked to keep a diary documenting the saliva and OMT collection, as well as basic compliance with collection instructions. These methods have been used in past research with men with cancer by the Dr. Hoyt and have been shown to be reliable and acceptable to participants. Instructions will be reinforced by providing participants a link to a brief online instruction video.

Intervention
GET draws heavily from the principles of Hope Therapy, with an emphasis on goal navigation skill building. This includes work on goal setting with a focus on assessing progress toward achieving specific, realistic, and measurable goals. Patients will be asked to identify value-derived goals (i.e., goals for the most important domains of one's life) and ones sufficiently important to sustain movement toward them in the short-term future. Patients will discuss their goal possibilities, providing a forum to ensure that goals are manageable and consistent with identified values. Patients will learn strategies to refine their goals (e.g., approaching goals rather than avoiding obstacles, defining markers of progress), generate pathways to goals, and address potential obstacles and blockages. Additionally, goals provided the context for demonstrations of agentic thinking (e.g., I will be able to do this) and interventions to increase agentic thinking. Specific attention will be given to career/education-related goals. Emotion regulation components will include basic cognitive restructuring skills, cognitive distancing, and coping efficacy skills (matching the correct coping skill to specific circumstances). The overall goal is to enhance self-regulation through improved goal navigation skills, improved sense of meaning and purpose, and better ability to regulate specific emotional responses.

GET has not been previously tested in the format utilized in this study. However, its components and theoretical underpinnings are solidly grounded in previous empirical work. GET relies heavily on aspects of Hope Therapy. Hope Therapy generated from a long tradition of work on Hope Theory (see Cheavens et al., 2006). It has been tested in a community sample and more pertinent to this application, has been administered as part of a larger intervention with breast cancer patients (Thornton et al., 2014). In both trials, Hope Therapy has been shown to be effective in improving overall

well-being. GET also includes components of emotion-regulation. Much therapeutic attention has been given to emotion-focused therapeutic work and skill-building. This approach has a significant empirical base and draws from supportive-expressive work with breast cancer patients (Giese-Davis et al., 2002), emotion-focused therapy techniques (Greenberg & Watson, 2006), acceptance and commitment therapy (Hayes et al., 2006), dialectical behavior therapy (Linehan et al., 1999), and expressive writing traditions (King, 2001). Thus, although GET is a novel compilation of approaches, its component parts have a significant empirical base.

GET will be delivered in 6 sessions. Sessions 1-4 are designed to be weekly sessions. Sessions 5 and 6 are spaced by 2 weeks. Each session will be 60 minutes in length. The sessions will be audio and video-recorded. Sessions will be delivered via Zoom, a secure online video communication platform made available to UCI researchers. On request, sessions will take place in person at either UCIMC or at the PI's lab on the main UCI campus. However, to accommodate participant's preferences sessions can be scheduled by telephone. This is stated in the consent information and will be offered to participants during session scheduling who inquire about this option or who express scheduling difficulties. Sessions conducted by telephone will be conducted exactly as if done over Zoom, including being audio recorded.

Study 2 will also utilize a time- and attention-matched control--Instrumental Supportive Listening (ISL).ISL is a predominant approach to community-based supportive care in psychosocial oncology. In this study, ISL is adapted from the Supportive Group Psychotherapy manualized intervention, and subsequently adapted further for use in our pilot work for young adult cancer patients. This intervention includes 6- sessions of individual supportive listening utilizing an approach based on models described by Rogers and Block, including components of genuineness, unconditional positive regard, and empathic understanding through reassurance, explanation, guidance, suggestion, and encouragement.

All participants completing the intervention and follow-up assessments will be given a total of $150 dollars ($50 at each assessment time) in cash, money order or a gift card. They will receive an additional $25 for participation in the qualitative interview (Study 1).

Selection, Training, and Supervision of Study Interventionists: Any additional study interventionists (aside from the PI) will be formally added to the IRB protocol. The manualized research intervention for this protocol is highly structured, and the session interventionist is provided with an outline of content for all study modules. Study interventionists will have received specialized training in GET prior to delivery. Supervision and training for interventionists will be conducted by Dr. Hoyt who has extensive training and supervision experience in these approaches, and will include both didactic and experiential training. All interventionists will be given an intensive training workshop in the delivery of GET prior to beginning, with a focus on the unique issues of young adults with cancer. These training workshops will focus on the acquisition of skills in the conduct of the sessions. All interventionists will be provided with a copy of the treatment guideline, describing in detail the philosophy, format, and techniques involved in the

approach. Dr. Hoyt will lead weekly group supervision sessions for the different providers. Interventionists will receive intensive supervision, and their competency in the approach will be continually assessed.

Study interventionists will minimally be a graduate student of Clinical Psychology, Mental Health Counseling, social work, health science, or psychology to qualify for consideration as an interventionist on this study. These interventionists will have been previously trained in general cognitive-behavioral approaches and in doing clinical intervention with chronically ill patients.

Treatment Integrity/Fidelity to Intervention Format: We will establish several procedures to monitor treatment protocol fidelity and improve standardized delivery of the treatment. First, we have developed standardized treatment manual. We have also developed a provider outline of intervention components for each session. These are included in the treatment manual, and checklists/outlines can be used to facilitate supervision. We have also developed a "Treatment Fidelity Checklist". Fidelity Forms allow for independent raters to evaluate each session for treatment fidelity in terms of process and content. Fidelity refers to assessing how closely the interventionist followed the intervention protocol in each session. It is not a measure of the participant's adherence. Its purpose is to quantify the question "was the intervention delivered as planned".

All sessions will be digitally recorded (audio & video) with prior consent of the participants. Notably, missing audio or video recordings due to technology malfunction will not be considered a study violation. A rater from the study team not including the interventionist will listen to the recordings to ensure compliance. In order to ensure reliability of ratings, Dr. Hoyt will rate the first two sessions evaluated by raters and discuss discrepancies in ratings in separate supervision sessions focused on reliability of ratings. Throughout the study, interventionists will be given feedback to enhance continued training and supervision.

Interviews (Study 1) will be conducted using a semi-structured interview guide. Participants will be reminded of confidentiality (and the limits of confidentiality) that were presented in the study consent form.

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.

Questionnaire Measures	Instruments
UCI Cancer Center Approval Letter	IRB Determination Letter
UCI IRB Amendment Approval Letter	IRB Determination Letter
UCI IRB Letter	IRB Determination Letter
Project Proposal	Other Documents
Interview	Questionnaires
Interview- Spanish	Questionnaires
Questionnaires - Spanish	Questionnaires
Translation Certification	Translator Curriculum Vitae

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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.).
Qualitative interviews will be digitally audio-recorded. Intervention sessions will be digitally audio- and video-recorded. Sessions will be heard by the PI and study staff for the purposes of clinical and study oversight as well as the coding of treatment fidelity. Recordings will be deleted/destroyed following fidelity coding. Recordings of the qualitative interview will be transcribed with any identifying information removed in transcription. Audio files will be destroyed/deleted following transcription. Transcripts will be used as data in qualitative analyses. Direct quotes (with no identifying information) may be used in scientific presentations or publications.

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	California Cancer Registry

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.

Participants will be 170 young adults with cancer who have completed treatment (including chemotherapy) using the following eligibility criteria:

Subject Inclusion Criteria
-Age 18 to 39 years at time of consent
-A confirmed diagnosis of testis cancer (Study 1 only)
-A confirmed diagnosis of cancer (all types; Study 2 only)
-Self-identified male gender
-Age 15-39 at diagnosis (Study 2 only)
-Completion of primary medical treatment for cancer
-Hispanic/Latino identification (self or cancer registry confirmed)
-A score of < 1.8 on the goal navigation scale or < 0.6 on the goal facility scale of the CAYA or >4 on the Distress Thermometer
-English or Spanish fluency, as per medical record documenting preferred language or in the judgment of the investigator
-Able to perform informed consent

Subject Exclusion Criteria
-Lifetime history of psychiatric of cognitive disturbance as per self-report or medical record
-In the judgment of the consenting professional, is unable to provide informed consent and complete study sessions and assessment
-As per self-report, has medical conditions that affect the immune system and would confound immune evaluation (e.g., autoimmune disorder, inflammatory disease; uncontrolled thyroid disease; active infection; myocardial infarction or stroke in the last 6 months; Type I diabetes; acute hepatitis; recent vaccination for viral disease)
-Regular smoker (daily use)

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.

We will be requesting data from the California Cancer Registry that match our eligibility criteria so that we can inform potentially eligible individuals about the study.

Name
Address
Telephone Number
Treatment Type
Cancer Diagnosis
Age
Ethnicity and/or Race

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.
No answer provided.

RATIONALE

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

Why Study Hispanic/Latino Young Adults with Cancer?
There is a strong need for attention to survivorship in this group and on interventions that control physical, psychological, and behavioral adverse effects of cancer in Hispanic/Latino young adult cancer survivors. Hispanics/Latinos are underserved in supportive cancer care and underrepresented in cancer survivorship research. Yet, they have higher rates of depression than other cultural groups and are therefore are at greater risk for cancer-related distress. This health disparity is becoming clearer among young adult survivors and young male Hispanic/Latino survivors may be at particular risk. In a study of young adult cancer survivors, Latinos scored higher in depressive symptoms and lower in quality-of-life compared to non-Latinos. Moreover, Latino males reported worse outcomes compared to whites and Latinas. Further, some evidence suggests that cultural factors or connection with Latino heritage is protective against depressive symptoms in young men after cancer. No study has examined enhancement of psychological adjustment in young adult Hispanic/Latino cancer patients. There is a clear necessity for feasible, effective, culturally-tailored, and scalable interventions.

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.

Primary recruitment will be conducted by contacting potentially qualified individuals identified through the California Cancer Registry. We will contact listed individuals by mail letting them know they can either contact us with interest, to tell us they are not interested, or to get more information. We will let them know that we will re-contact them again by mail or telephone to follow-up. We will use the screening script to screen all interested individuals.

We will also recruit via referral from colleagues:
• Study team will provide colleagues with UCI IRB-approved recruitment materials for distribution to potential subjects (e.g., introductory letter, clinic staff script); [Clinic staff are not engaged in research procedures beyond simple referral of interested individuals to study team]
• An IRB-approved recruitment letter will be sent by the treating physician. The letter will be signed by the treating physician and sent to his/her patients to inform them about how to contact study team members.
• Colleagues obtain permission from interested patient to release contact information to researchers.

Other Recruitment Methods: Study team will screen UCIMC medical records via EPIC and the UCI Honest Broker mechanism. The patients' physicians will be informed prior to the team contacting the patient to allow the physician the opportunity to inform the study team that the patient should not be contacted (for whatever purpose the physician deems appropriate). No further action would be taken. For other patients, the study team will send the patient and informational letter and will contact the patient directly no sooner than 2 weeks after sending a letter (unless the patient indicates he would not like to be further contacted).

Attach copies of all recruitment materials.

Recruitment Letter	Recruitment Materials
Recruitment Letter (Spanish)	Recruitment Materials
Study Introduction Script- Clinical	Recruitment Materials

Deleted Attachments: 4 (Most Recent: Study Introduction Script on 05/23/2024 4:21 PM ET)

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.
The screening script will be used to conduct the screening procedures. In addition, all individuals interested in participating will complete a 12-item screening (~5 min) with two subscales from the CAYA (either in person or over the phone). Participants who score < 1.8 on the goal navigation scale or < 0.6 on the goal facility scale of the CAYA or >4 on the Distress Thermometer will be invited to participate. If individuals decide they are not willing to complete a screening questionnaire, no further follow up will be conducted. As this procedure presents no more than minimal risk to the privacy of the individuals who are screened and only minimal personal information (PHI) will be maintained as part of the screening log, a (partial) limited waiver of authorization will be sought for the purposes of (1) conversing with patients regarding possible enrollment; and (2) maintaining information in a screening log of patients approached.

The screening process for the protocol requires administration of screening questionnaires. In following the Code of Federal Regulations Title 45, Part 46, Subpart A, which states that an IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, a signed consent may not be required for this study. In accordance with the aforementioned regulations, we request to waive consent for identifying whether the patient is eligible, which includes administering the pre-screening measures.

If a participant is ineligible for the research study, the research staff will destroy all information collected during the initial eligibility determination, except for any minimal information maintained for screening log purposes (e.g., age, race, ethnicity, outcome of approach, and reasons for ineligibility). We will also maintain a list of all participants approached throughout the entire study to record reasons for refusal and avoid approaching patients multiple times if they have been identified as ineligible or refusers. This list will be destroyed at the completion of the project.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card
Cash

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.
All participants completing the intervention and follow-up assessments will be given a total of $150 dollars ($50 at each assessment time) in cash, money order or a gift card. They will receive an additional $25 for participation in the qualitative interview (Study 1 Only).

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 total duration period of participation is approximately 5-6 months. This includes completion of baseline assessments (~1.5 hours), participation in 6 intervention sessions (~6 hours), completion of T2 assessments (~1.5 hours), completion of T3 assessments (~1.5 hours), 12 total days of at-home saliva collection (~15 minutes each), and completion of the qualitative interview (~1 hour; Study 1 only).

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.

This study meets the following 45 CFR 46.110 categories for Expedited Review:

Category #3: Collection of samples by non-invasive means.
All of the biological samples for this study are collected via oral swab or saliva swab. These are non-invasive methods, involve no venipuncture, and have no associated anticipated risks.

Category #7: Data is collected by survey and interview.
Psychological and behavioral data will be collected solely via online survey questionnaires and/or direct interview with the research team.

Minimal risk of psychological distress is posed by study questions that ask participants to discuss their mental and physical health, relationships, and other personal subjects. However, since study items and topics were chosen to reflect what are likely to be existing concerns, the present study is not expected to markedly increase participants' psychological distress above their routine concerns. (Rare and mild)

Despite significant efforts to protect private information, there is also the possibility that confidentiality could be breached. There is also one exception to strict confidentiality, which pertains to information obtained during the research assessment which would indicate that the patient is seriously suicidal and may pose a significant and acute risk of self-harm or harm to others. Participants will be informed of this exception, and will also be informed that timely and appropriate psychiatric assessment and care can be provided by a local hospital, mental health provider (other than the PI), or primary care physician. If a participant at acute risk of self-harm or harm to others cannot be reached (after at least two phone call attempts and an email requesting a call back), the participant's emergency contact(s) will be contacted. If an acutely distressed individual who denies active suicidality or homicidality cannot be reached within 24 hours (after at least two phone call attempts and an email requesting a call back), the participant's emergency contact(s) will be contacted. These details are outlined in the informed consent. In both cases, any other mental health providers the participant has been under the care of or physicians prescribing psychotropic medication will be notified as well. (Rare and moderate)

AUDIO/VIDEO RECORDING RISKS

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

Despite significant efforts to protect private information, there is also the possibility that confidentiality of audio or video files could be breached. All files will be labeled with participant codes only and saved in a password protected computer file at UC Irvine.

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.

N/A

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.

Although not recording intervention sessions would be less risky, recording sessions are integral to both coding for treatment fidelity and for supervision of interventionists. However, recordings are not transcribed and all recordings will be destroyed following coding. Also, as mentioned screening data will be rendered immediately anonymous. We will only maintain contact information of ineligible individuals to ensure we do not re-contact them.

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.

This study has potential to contribute knowledge to our understanding adjustment to testicular cancer and the identification of potential clinical interventions to promote better adjustment.

JUSTIFICATION OF RISKS

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

To minimize any potential risks or discomfort associated with participation in this study, participants will be reminded that they may withdraw from the study at any time without penalty and will be informed that they may choose not to answer any questions or perform any part of the assessments that cause them discomfort. In addition, we will also offer all participants information regarding community mental health resources, including a 24-hour suicide prevention hotline. They will also be informed during the consent process that in the event that they tell the research staff they are thinking about killing themselves or if they answer "yes" to a question about having thoughts about suicide, that the investigator will ask them more questions about their thoughts and that the research staff may provide them with referrals for treatment, work with them to contact their family, or take other measures to ensure their safety.

Participants will be informed that participation is voluntary and that they have the right to withdraw and/or leave any question blank if they do not feel comfortable answering. Given the potential gains to participants, the ratio of risk to benefit is quite low and reasonable. Confidentiality of each subject's self-report information and each patient's medical information will be protected with the utmost care. Each study subject will be given a unique numeric identifier upon study entry. Data collected from each subject will be identified solely by a code number. A list matching subject names and code numbers will be maintained separately and kept in a secure area. IRB and HIPAA regulations concerning confidentiality will be strictly enforced. Any hardcopies of the original questionnaires will be stored in locked file cabinets.

Through the use of password security measures, restrictions will be applied to each user commensurate with their needs to access the data. Confidential information will not be routinely available to all members of the research team but rather on a 'need to know' basis. All current and new personnel will be instructed in the ethics of electronic data access, as well as receive training in both HIPAA issues and human subjects training.

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
Medical record number
Internet Protocol (IP) Address

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 staff undergo UCI IRB training on confidentiality and protections of human subjects, which includes a specialized training module on HIPAA. All staff also receive training and oversight by the Principal Investigator. Each will sign a confidentiality agreement specific to this study.

STAFF VETTING PROCEDURES

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

All staff are affiliates of UC Irvine and undergo standard vetting procedures according to university policies and procedures. All project staff have relevant experience commensurate to their duties.

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.

California Cancer Registry Support Letter Other Documents

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.

Data acquired from the California Cancer Registry (CCR) will only be used in strict accordance with the procedures outlined in this protocol and approved by the CCR. All CCR data will be deleted/destroyed immediately following sanctioned use and planned procedures.

Through the use of password security measures, restrictions will be applied to each user commensurate with their needs to access the data. Confidential information will not be routinely available to all members of the research team but rather on a 'need to know' basis. All current and new personnel will be instructed in the ethics of electronic data access, as well as receive training in both HIPAA issues and human subjects training.

CONFIDENTIALITY OF PUBLISHED DATA

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

Confidentiality of each subject's self-report information and each patient's information will be protected with the utmost care. Each study subject will be given a unique numeric identifier upon study entry. Data collected from each subject will be identified solely by a code number. A list matching subject names and code numbers will be maintained separately and kept in a secure area. IRB and HIPAA regulations concerning confidentiality will be strictly enforced. Any hard copies of the original questionnaires will be stored in locked file cabinets. Data will only be reported in aggregate. Participants will never be identified by name or by any other personal identifier.

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?

We have successfully recruited this population in prior trials from the CCR. In a prior study of 18 – 29 year old testicular cancer survivors, one registry query identified 694 eligible cases that ultimately yielded a 59% participation rate (171 young men) [39]. This participation rate is significantly above the yield typical for CCR survivor studies, and might demonstrate a particular need or desire to participant within this survivorship group. However, it should be noted that this prior study was not an intervention study, had less restrictive entrance criteria, and involved less participant time than the current study. The proposed study will use a broader age range (18-39 years), cancer diagnosis (all cancer types), and (given the entrance criteria) will have the ability to query the CCR at least twice in the course of the study to identify unique cases.

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.

All study data will be available to study staff and researchers on a need to know bases, enforced by the PI.

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.

The 2 study groups are determined by randomization and therefore will not be designated by any indicator that could be identifiable.

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*

CPHS Security Attestation - Michael A Hoyt uci-20-20 signed.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 be de-identified

Explain what identifiers will be removed and how.
All 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.

Any PID in paper form will be destroyed via cross cut shredding per University provided services.

FAXING

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

Faxing will be seldom used and not a planned method of document transfer. However, the PI maintains a private fax machine in a secure room only accessible by the immediate research team.

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.

All mailings of PID will be sealed and secured from inappropriate viewing. No single mailing of PID will contain more than 500 or more individually identifiable records.

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.

Data will never be left unattended during transport. Laptop computers and portable electronic storage media (e.g., USB drives and CDs) will be encrypted and will never be left unattended in any unsecured locations. Some data will be accessible for at-home work. All accessible data will not be stored locally - but only on secure UCI servers as noted. All files will be password protected and accessible on a need to know basis. Also, all patient data to questionnaires will be stored with only their participant number.

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.

The PI has dedicated research space at UC Irvine that has controlled access and 24 hour security by the UCI on campus Police Department. Only members of the PI's immediate team have access. The dedicated space includes ample key-locked storage.

SERVER SECURITY

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

UCI maintains server security at the departmental level. All servers supporting this project are housed in a secure facility with access only to appropriate personnel on a controlled basis.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Only 1 list connected participant codes with personal identifiers will be maintained and kept separate from all data. This list will be controlled by the PI and accessed by study team members on a need to know basis.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID (if used) will be destroyed at the end of the study, and locked in a cabinet until destruction. However, no external disks are planned for use in this study.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computer access related to study activities will be protected through the use of encryption (including electronic audio files), and password protection (including computer log on in research offices).

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.

PID will not be stored on individual workstations. However, all stations use FIPS 140-2 compliant software in accordance with UCI Health Sciences data security procedures.

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.

PID will not be stored on individual laptops. However, all laptops will be UC Irvine-issued machines and thus use FIPS 140-2 compliant software in accordance with UCI Health Sciences data security procedures.

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.

We do not use removable media devices for the storage or transport of PID.

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.

The PI's research laboratory is maintained by UC Information Technology Services which involves regular service updates and protection assurance.

PASSWORD CONTROLS

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

UCI uses a two-tiered authentication (Duo Factor Authentication) for the highest level of password control for all university machines and applications.

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.

No PID will be accessed at publis worskstations. However, all machines will timeout after 8 minutes of inactivity (within the PIs laboratory). Further, the university provides virus protections and intrusion detection services to all study machines.

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.

The UCI HS server meets UCI compliance with encryption standards on email and other electronic communications.

INTERNET ACCESSIBILITY

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

No PID will be accessible via internet.

DISPOSING OF PID

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

When disposing of PID we will engage in secure wiping procedures in consultation with our dedicated UCI IT 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.

Signed informed consent will be obtained from subjects. Given that subjects may not be physically present. Consent information will be delivered over the phone and/or in writing. Signature will be obtained via UCI DocuSign. Subjects will have unlimited online access to the consent document. They will have the opportunity to take unlimited time to review the consent information, consider participation, or talk to the study team with questions.

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.

Revised Consent Form - Spanish	Consent Form
Revised Consent Form (Study 2)	Consent Form
Revised Consent Form-Spanish (Study 2)	Consent Form
Revised Consent-Spanish w/tracked changes	Consent Form
Revised Consent-w/tracked changes	Consent Form
Revised Consent-w/tracked changes	Consent Form

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

No

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?

Yes

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?

No

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.

Waiver/alteration approved by another IRB that reviewed this project.

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.

appendix T.doc HIPAA Documents

Amendment Changes

List the pages and questions that have been changed.

Page 3
-Project Title
-Anticipated Project End Date

Page 4
-Purpose
-Major Research Question
-Study Procedures & Attachments
-Recording

Page 5
-Populatiion Decription
-Rationale
-Recruitment Details & Attacheents
-Screening
-Compensation
-Study Duration

Page 6
-Audio/Video Recording Risks

Page 11
-Informed Consent Procedures
-Consent Forms

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

CFCCC Budget (Study 2)- Additional Funds	Project Budget
CFCCC-Budget.pdf	Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover Letter2.pdf 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: California Cancer Registry

PI Signature for Coordination Submission (Amend) - Submitted 05/23/2024 4:50 PM ET by Michael A Hoyt, 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 Thursday, May 23, 2024 4:50:15 PM ET by Michael A Hoyt, PhD

Notify IRB for Pre-Screening
- Submitted 12/17/2024 4:20 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)

Expedited

Please provide a rationale for your level of review preliminary determination
PI is requesting to expand the protocol to include young adult male Hispanic/Latino cancer patients of any type, not just testicular cancer as previously approved.
Below is a summary of changes made to the consent form: (1) Revised all mentions of testicular cancer to broadly "cancer", (2) Clarification of saliva collection timing, (3) Removal of qualitative interview option (the study team obtained sufficient qualitative data from the initial cohort of participants and will no longer be conducting qualitative interviews with new participants), (4) Revision of sample size from 70 to 170 Latino YA cancer survivors, (5) Removal of treatment time window requirement, (5) Addition of inclusion criteria--diagnosed between the ages of 15-39, (6) Addition of consent to video record along with already approved audio recording, (7) Addition of REDcap to remove Qualtrics, and (8) Addition of a follow-up assessment (at 3-months). PI will also be requesting additional data from the California Cancer Registry to facilitate recruitment of this new population.

(reassigned from Dr. Bazzano, both the amendment and CR application have been re-assigned to Dr. Dickey)

Choose the primary expedited reviewer for this project
Larry Dickey, MD, MPH, MSW

Choose 'expedited'.
Expedited Review

Choose the staff member who should be notified when the reviews are completed (normally this will be the person processing the review, but if you will be OOO, you are able to chose someone else):
Nicholas Zadrozna

Assign to Cycle

August

Assign to cycle year
2024

Load into IRBManager (Amendment)
- Submitted 12/17/2024 4:20 PM ET by The System

Under Expedited Review

Expedited Review

Project Number *(Internal)*

2020-112-UC Irvine

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'.

Complete your review using the link in the review email you received in order to record your review determination.

review list output Note: The reviewer's determination will not appear on this table until the reviewer has complete the review form.

Type	Reviewer	Outcome	Assigned	Due	Complete
Expedited Review	Larry Dickey, MD, MPH, MSW		12/17/2024	12/27/2024	

Reviewer feedback for amendment (used to pull into email)