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 11/05/2025 1:02 PM ET by Michael A Hoyt, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

December 2025 cycle.

_____New HSC Project_____

09/24/2025 • Sussan Atifeh • Internal

Dear Researchers: Please review all pages of the application (be sure to scroll down to view each page), address the comments, and resubmit the application.

The submission deadline for the December 2025 cycle is November 7th. If you need additional time to make revisions, you may disregard any automated emails from IRBManager requesting resubmission within 3 days of return to data entry. Instead, please ensure the application is fully updated and all comments are addressed and resubmitted by November 7th.

Thank you.

10/14/2025 • Sussan Atifeh • *Not* Internal • Resolved

Researchers from UCI have submitted this application to request approval for a project with human subjects' contacts that is aimed to understand how long-term young adult survivors of testicular cancer who were diagnosed at ages 18–39 and now at least five years post-diagnosis, continue to use self-regulation skills like goal-setting and emotion management. These skills are the focus of a therapy called Goal-focused Emotion-Regulation Therapy (GET), which has shown promise in recently treated patients. By examining how these processes relate to psychological, social, and occupational outcomes later in survivorship, the study aims to determine whether GET could be adapted to support long-term well-being and guide future interventions and survivorship care.

Main site of the Study:
University of California, Irvine (UCI)—A DSL from UCI was attached on 11/5/2025.

Data-Source Department(s):

California Department of Public Health (CDPH)/(CCR)California Cancer Registry—A LOS from CCR was attached on 11/5/2025.

End Product of the Project: No Response.

Funding:
Federally funded by National Institutes of Health (NIH)—Project's budget is attached.

Linkage: No

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If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact 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.

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Michael A Hoyt, PhD

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

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

University of California, Irvine

Enter the city in which the PI's institution is located.
Irvine

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.

California

Attach a copy of the PI's Curriculum Vitae.

CV 2025-2.pdf PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

No answer provided.

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Michael A Hoyt, PhD

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

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Beverley Alberola, PhD

Email: Beverley.alberola@uci.edu **Business:** (949) 824-5746

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

Please ensure you have listed in this section "all" research staff who interact directly with participants (as in interviews or focus groups) or who will have access to the data.
• This includes individuals who will have access to the linked de-identified data if that data file will contain any data fields that were originally in the state data.
• This includes all research staff who are involved with data management, data processing or analysis and write-up, etc.

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Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

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

Karen Llave, MPH
Email: kllave@hs.uci.edu **Business:** (323) 868-3392

David Zoeter, BA
Email: zoeterd@hs.uci.edu **Business:** (949) 824-5281

Check for PI same as RO (internal only question) *(Internal)*

False

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).

Understanding Adverse Biopsychosocial Outcomes and Unmet Needs Among Long-Term Young Adult Survivors of Testicular Cancer

PROJECT SITE

Indicate the primary site at which the research will be conducted.

University of California, Irvine

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)*

SB-13 (Information Practices Act)
Common rule/Human subjects

PROJECT TYPE DETAILS

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

Please de-select 'HIPAA Waiver' if you do not need to request a HIPAA Waiver from CPHS.

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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.
Federally funded

Enter name of federally-funded source.
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.

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. This project belongs to the December cycle. Please change this date to 12/5/2025.

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

12/05/2025

ANTICIPATED PROJECT END DATE

10/31/2028

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.

Please name the main (primary) site of the study in this section.

Note: The main (primary) site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator's institution, which houses and manages the servers through which the data is processed.

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Please briefly describe the expected end product(s) of this project—for example, a research report, journal article, thesis or dissertation, webinar or presentation, policy brief, recommendations for practice or policy, pilot program, or other relevant outputs.

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Testicular cancer (TC) is the most common malignancy among adolescent and young adult males, with peak incidence between ages 20–34. While survival rates exceed 95%, long-term survivors remain at risk for persistent psychological distress, occupational disruption, cognitive complaints, and other adverse biopsychosocial impacts. Despite the growing population of long-term TC survivors, research on the psychosocial and biobehavioral mechanisms that contribute to these late effects is limited, particularly among those diagnosed during young adulthood—a developmental period marked by identity formation, career exploration, and goal pursuits.

Our team at the University of California, Irvine (primary site) is currently conducting a randomized controlled trial of Goal-focused Emotion-Regulation Therapy (GET) in young adult testicular cancer survivors. Preliminary data suggest GET may reduce mood symptoms, improve goal navigation, enhance management of emotions, and modulate stress biology. Although the conceptual model underscoring GET purports that enhancement of such skills could have a long-term positive impact, it remains untested whether

these core mechanisms generalize to long-term survivors—those who are more than five years from diagnosis—and whether these skills continue to shape psychosocial and occupational outcomes later in survivorship.

The objective of this cross-sectional study is to evaluate biopsychosocial and occupational correlates of self-regulation in a sample of 125 long-term young adult TC survivors (5 years of more post-diagnosis, diagnosed between ages 18–39). We will assess depressive and anxiety symptoms, cognitive concerns, fatigue, health-related quality of life, and occupational factors (including financial toxicity). We will also measure goal navigation, emotion regulation, and personal agency (core processes of the GET intervention). In analyses, we will characterize symptom burden in long-term survivors and examine associations between goal navigation and psychosocial, occupational, and biological outcomes to further inform intervention development. Further, understanding whether the self-regulatory processes targeted by GET are relevant in later survivorship will inform future intervention tailoring, survivorship guidelines, and theoretical models of cancer adaptation.

MAJOR RESEARCH QUESTION

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

The objective of this cross-sectional study is to evaluate biopsychosocial and occupational correlates of self-regulation in a sample of 125 long-term young adult testicular cancer survivors (=5 years post-diagnosis, diagnosed between ages 18–39).

The aims of this study on long-term cancer survivorship are:

Aim 1: Characterize the biopsychosocial and occupational symptom burden in long-term young adult testicular cancer survivors, along with mechanistic constructs targeted by GET. We will assess depressive and anxiety symptoms, cognitive concerns, fatigue, health-related quality of life, and occupational factors (including financial toxicity). We will also measure goal navigation, emotion regulation, and personal agency (core processes of the GET intervention).

Aim 2: Evaluate associations between goal navigation and psychosocial, occupational, and biological outcomes. Based on prior research linking goal processes to psychological health and adjustment in cancer [5,9], we hypothesize that better goal navigation will be associated with reduced distress, enhanced quality of life, improved occupational functioning, and greater individual agency.

Aim 3: Examine emotion regulation in relation to biopsychosocial and occupational outcomes. Emotion regulation difficulties have been consistently linked to distress, impaired functioning, and dysregulated physiological stress responses in cancer populations [10]. We anticipate that greater capacity in adaptive emotion regulation skills will be associated with more favorable outcomes across all domains, paralleling patterns observed in recently diagnosed survivors [9].

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

> Please make sure that all acronyms are spelled out in full with the abbreviation in parentheses the first time they appear in each section of the application.
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Participants will be recruited from the California Cancer Registry, from outpatient clinics, and through the University of California, Irvine Medical Center (UCIMC) and Children's Hospital of Orange County (CHOC), as well as through advertisements to community cancer and health care organizations.

Identified individuals will receive a recruitment letter, study flyer, and study information sheet via mail or email. These materials will contain a link to a REDcap survey and a unique code. If a person does not respond to the initial attempt at contact, the research team will call them two weeks later and ask if they would like to learn more about the study. If this contact is unanswered, we will give them one additional call two weeks later. No further contact will be made if they are unreachable or indicate that they would like to be removed from the call list.

When accessing the REDcap link, individuals will be asked to input their unique code. They will then undergo a self-screening to determine if they meet the study eligibility criteria by answering several questions on REDcap (see the pre-screening document). If eligible, they will gain access to the study information sheet and the study questionnaires (see formatted measures below). If a participant is ineligible, the research staff will destroy all information collected, except for any data maintained for tracking 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. If an individual decides not to complete the screening questions, no further follow-up will be conducted.

After completing the questionnaires, participants will be taken to a separate survey and asked to provide their name (first and last) and mailing address. This information will be used to distribute compensation and will be maintained separately from study data. Participants will receive a $130 VISA gift card for completing the questionnaires. Once compensation is sent, their participation ends, and they will be considered off-study. While the survey may take 1.5 to 2 hours to complete (including the screening questions, which should take <5 min.), the study team may take up to 5 business days

to produce and mail the gift cards.

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.

LTS Formatted Measures 9.24.25_clean.docx	Instruments
UCI IRB Approval Letter	IRB Determination Letter
Screening Questionnaire	Other Documents
UCI Project Protocol	Other Documents

Deleted Attachments: 1 (Most Recent: LTS Formatted Measures 9.24.25_clean.docx on 10/15/2025 6:00 PM ET)

RECORDING

Will audio or video recording occur?

No

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 125 young adult testicular cancer survivors. The following eligibility criteria will be used.

Inclusion criteria include:
-Are between the ages of 23 and 39 years at the time of consent
-Has a confirmed diagnosis of testis cancer (any stage) at least 5 years prior
-Diagnosed with testicular cancer at age 18 or older
-Completion of chemotherapy for any cancer
-Can provide informed consent

Exclusion criteria include:
-Lifetime history of bipolar disorder, schizophrenia, schizoaffective disorder (per self-report)
Presence of disorder that compromises comprehension of assessments or informed consent information (e.g., dementia)

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.

Could you please attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in this section?
In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables. Thanks.

• If you do not have access to the formal data dictionaries, you can create a Word or Excel document to list all the variables. Include three columns:
1. Name of Variables: List the requested variables.
2. Justification: Provide a brief explanation justifying the request for each variable.
3. Usage of Variables: Explain how each variable will be used.

• If you are using any publicly available data sets, please provide a separate list of the variables that will be used from public records and explain their relevance to the study.

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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 request data from the California Cancer Registry that matches our eligibility criteria, enabling us to inform potentially eligible individuals about the study. Contact information will be used to send recruitment materials.

Please see the attached list of variables requested. Participants will not be involved in any other studies unless they provide written permission (in the Study Information Sheet) for the study team to contact them for future research.

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.

Requested_Variables_ADA_LTS.xlsx List of Variables

RATIONALE

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

Psychosocial Late Effects in Young Adult Testicular Survivors

Epidemiological studies confirm that for young adult males, testicular cancer (germ cell and trophoblastic neoplasms of gonads) has the highest cancer incidence (18.5% of cancers). Most are diagnosed at ages 25 to 29 years (26.6%) or 30 to 34 years (26.3%). Due to high survival rates exceeding 95%, testicular cancer survivors represent a growing cohort with unique survivorship needs. The majority are diagnosed during young adulthood (age 18 to 39), a developmental period characterized by transitions in identity, independence, intimacy, and future planning. A diagnosis during this time can cause profound disruption to life goals, psychological development, and social integration. While medical follow-up care for late physical effects is better established, attention to long-term psychosocial outcomes remains insufficient.

Research indicates that testicular cancer survivors are at elevated risk for persistent depression, anxiety, and fear of recurrence. Studies suggesting up to 20–25% may experience significant emotional challenges years post-treatment. In young adults, these experiences are often compounded by identity challenges—related to masculinity, sexuality, and fertility—as well as disrupted life trajectories including educational attainment, romantic relationships, and career planning. Social disruptions are also prominent. Many survivors report feeling isolated from peers, lagging behind in career and educational pursuits, and struggling with long-term planning. Yet, these experiences are often unaddressed by care models focused on physical recovery and a comprehensive, longitudinal, and developmentally tailored framework for understanding and addressing biopsychosocial issues is needed.

Self-Regulation and Goal Pursuits in Long-term Survivors

Long-term survivors often experience shifting psychosocial demands—such as evolving priorities, financial strain, and career disruption due to unfolding cancer-related adverse impacts—that might benefit from different or sustained forms of intervention. For instance, even years after treatment, young adult survivors frequently report concerns about future planning, self-efficacy, and emotion regulation in the face of ongoing uncertainty.

Adjustment to challenged goals constitutes adaptive self-regulation and may be particularly critical when cancer occurs in early adulthood. In fact, our extensive work with young adult testicular cancer survivors identifies the key self-regulatory processes of goal adjustment and emotion regulation after cancer, as critically related to relevant health outcomes, at least in those more recently diagnosed.

Theories of self-regulation assume that management of personal goals can promote well-being by providing structure for building a successful life and engaging in meaningful activities. Goal navigation skills include the ability to identify new and existing goals, which serves to support cancer-related well-being. Adaptive adjustment to goals that are impeded or blocked include the ability to disengage from goals that are no longer attainable and to pursue realistic goals. Effective goal adjustment is associated with higher subjective wellbeing, whereas relentless pursuit of unattainable goals can compromise health. At the same time, reengagement in meaningful alternative goals is associated with positive changes in self-perception, interpersonal relationships, and sense of life purpose. Cancer survivors often need to readjust goals to be more achievable than pre-diagnosis goals. Longitudinal data in colorectal cancer patients show that effective goal navigation capacity is associated with physical well-being over time.

Underscoring the significance of this study, our data-supported conceptual framework purports that self-regulation through goal navigation capacity and emotion regulation are developmentally-matched intervention targets and research on behavioral interventions to reduce adverse cancer outcomes for young adults has been scant. Building from this conceptual framework, we developed Goal-focused Emotion-Regulation Therapy (GET) as a novel behavioral intervention developed 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. Briefly, the GET intervention has a strong theory-driven base that guides targets for change and specific intervention technique. These include Stress and Coping Theory and Emotion Regulation Theory to underscore core emotion regulation components, Hope Theory to guide goal navigation skill building, and Self Determination Theory to build agency and mastery. A current project is aimed at testing the efficacy of GET in recently treated young adult testicular cancer survivors. Although the conceptual model suggests that enhancement of such skills could have a long-term positive impact, it remains untested whether these core mechanisms generalize to long-term survivors—those who are more than five years from diagnosis—and whether these skills continue to shape psychosocial and occupational outcomes later in survivorship. Thus, the current study is focused on testing the relationships that underscore GET in long-term young adult survivors of testicular cancer. Evaluating whether the processes targeted by GET remain associated with these outcomes in later survivorship will support adaptation of the intervention to better match the developmental and contextual needs of survivors across time.

Innovation

This study is innovative in its focus on biopsychosocial and occupational adaptation of long-term young adult testicular cancer survivors, a group in which a substantial proportion experience persistent psychological distress, cognitive difficulties, and disruptions in educational and occupational functioning in long-term survivorship. Few studies have addressed the modifiable psychological mechanisms that may underlie adverse outcomes across the survivorship continuum.

This project has potential to move forward the field through its careful focus on intervention targets. These include two core, developmentally salient self-regulatory mechanisms—goal navigation and emotion regulation—that are central elements of the GET intervention currently being tested in a randomized controlled trial with recently diagnosed young adult testicular cancer survivors. The current study is the first to evaluate whether these constructs remain relevant and impactful five or more years post-diagnosis, thereby directly testing the generalizability and theoretical robustness of the GET intervention model in longer-term survivorship.

By linking these mechanisms to biopsychosocial (including occupational) outcomes in a cross-sectional sample of long-term TC survivors, this study addresses a critical gap in survivorship science. It could inform the adaptation and scalability of GET for long-term use, guide tailoring of intervention strategies based on survivorship phase, and provide empirical support for refining conceptual models of self-regulation in cancer adaptation. This innovative approach lays essential groundwork for future longitudinal and intervention studies aimed at sustaining well-being and functioning well beyond the acute recovery period.

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. A study team member will then follow up via phone after two weeks (unless the individual indicates that they would not like to be further contacted). 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]
• 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 study team will then send the patient an 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.

Study Flyer	Recruitment Materials
Study Letter	Recruitment Materials

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. Participants will respond to the screening questions via a UCI-approved REDCap questionnaire. 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 who complete the questionnaires will receive a total of $130 in the form of a VISA gift card.

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 questionnaire will take about 1.5-2 hours to complete.

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 #7: Data is collected by survey and interview.
Psychological and behavioral data will be collected solely via online questionnaires.

The following risks are possible:
Psychological discomforts. Although the questions asked in the survey will mostly consist of validated, widely used and scientifically accepted psychosocial measures, some may cause embarrassment or anxiety, or they may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop. (Rare and mild)

Confidentiality. There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. (Rare and moderate)

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.

Not applicable.

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.

Not applicable.

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.

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

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 CITI training on confidentiality and the protection of human subjects, which includes a specialized HIPAA training module. All staff also receive training and oversight by the Principal Investigator and the UC Irvine. 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.

Please obtain and attach a Support Letter from the State department(s) that you have requested data from to conduct this study following the format specified on CPHS website. Applications without a Support Letter cannot be assigned to the CPHS committee members and will be returned back to you.

Please note that a "Support Letter" is NOT an Approval Letter. Rather, it is a statement that certifies that a "preliminary" or "initial" review has been conducted by the data-source department, ensuring that the release of data will comply with all applicable state and federal statutes.

For your convenience, you can access the acceptable template for a support letter using the links below:
https://www.cdii.ca.gov/wp-content/uploads/2024/10/Departmental-Support-Letter-Template-Revised-on-October-8th-2024.pdf

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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.

CPHS_LOS_Hoyt, M.docx.pdf Department Letter of Support

Deleted Attachments: 1 (Most Recent: LOS Pending_Email Communication.pdf on 10/30/2025 6:32 PM ET)

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 and in accordance with the California Health and Human Services Data De-Identification Guidelines (CHHS DDG). 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 be reported only in aggregate; researchers will suppress small cell sizes and follow the CHHS DDGs when analyzing and presenting data. 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 the California Cancer Registry (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). 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 Principal Investigator.

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.

To comply with California Health & Human Services Agency (CalHHS) Data Deidentification Guidelines (DDG), researchers must ensure that no cell size smaller than 11 is reported to prevent potential re-identification of individuals.
Please describe your de-identification methodology, including:
• How small cell sizes are suppressed and whether the CalHHS DDG standard (minimum cell size of 11) is being followed.
• Any additional suppression techniques used beyond the standard guidelines.
Providing a detailed explanation will help reviewers verify compliance with privacy and data protection standards.

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Data will be analyzed in aggregate, with no cells smaller than 10 used in analyses or reporting, following the CalHHS DDG standard. The researchers will follow the standard guidelines outlined by the CalHHS DDG standard, including (but not limited to) reducing the granularity of variables and using symbols to represent cells that have been suppressed.

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.

No

DATA SECURITY LETTER

Please obtain a Data Security Letter (DSL) from the Primary Site(s) of the study (using the format specified on the CPHS website) and attach it in this section ("Data Security Letter" section) of the application.

The Primary site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator's institution, which houses and manages the servers through which the data is processed.

Please note that the Data Security Letter (DSL) must be signed by the Chief Information Officer, Privacy Officer, Security Officer, or an equivalent representative of the researcher's institution, confirming that CPHS Data Security Standards are met.

For your convenience, you can access the relevant resources using the links below:

• Data Security Letter Template
https://www.cdii.ca.gov/wp-content/uploads/2024/03/Data-Security-Letter-Template-Accessible.pdf

• Data Security Requirements
https://www.cdii.ca.gov/wp-content/uploads/2023/04/Data-Security-Requirements-2012-04-20.pdf

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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_Data_Security_Attestation--Michael_A_Hoyt_UCI_(LTS).pdf	Data Security Letter

Deleted Attachments: 1 (Most Recent: Data Use Agreement_Signed.pdf on 10/30/2025 6:37 PM ET)

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 principal investigator 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 Principal Investigator 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.

UC Irvine 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.

UC Irvine 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 public worskstations. However, all machines will time out after 8 minutes of inactivity (within the PIs laboratory). Further, the university provides virus protection 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 UC Irvine Health Science server meets UC Irvine compliance needs 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 UC Irvine Information Technology 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.

A study information sheet will be provided to all participants via the REDCap survey link. They will be able to download a copy and study staff will be available to answer any study related 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.

Study Information Sheet Consent Form

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

Yes

Provide a rationale as to why the research could not practicably be conducted without the waiver or alteration.
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. Participants will self-screen via UCI REDCap, then have access to the study information sheet and the questionnaire.

Provide a detailed account of the plans and measures that will be in place to protect the rights and welfare of the subjects.
Participants will be made aware that their participation is entirely voluntary. They will also be advised that they can skip any question that they do not wish to answer. Additionally, contact information for the study team will be provided on the screening questionnaire, the study information sheet, and the study questionnaires.

Participants will be provided with a unique code, via the recruitment material, in which to indicate on their online questionnaire. A participant's address will be collected via a seperate questionnaire after they have completed the questionnaire.

We will also provide a resource sheet that provides information on a 24-hour Suicide Prevention Hotline and about organizations that support young cancer survivors.

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?

Please check with CCR to see if the requested data is covered under HIPAA. If not, please change your response in this section to "No."

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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.

HIPPA Authorization Document HIPAA Documents

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

Hoyt_NIH-NCI Supplement Budget-050725.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

LTS Cover Letter.docx Cover Letter

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 Wednesday, November 5, 2025 1:02:43 PM ET by Michael A Hoyt, PhD

In order to submit this form, click "Next" and "Submit." At that time, the application will be routed to the Responsible Official (if this is the first submission) for review and signature.

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

California Department of Public Health: California Cancer Registry

Responsible Official Signature
- Submitted 09/22/2025 3:14 PM ET by Beverley Alberola, PhD

Responsible Official Signature

After reviewing this application, is it ready for submission to the CPHS IRB?

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.

Signed Monday, September 22, 2025 3:14:21 PM ET by Beverley Alberola, PhD

After choosing whether or not the submission is ready for CPHS IRB review, please click "next" and "submit" (on the next screen) to move the form forward to the CPHS IRB or back to the Researcher.

Notify IRB for Pre-Screening
- Submitted 11/05/2025 5:50 PM ET by Sussan Atifeh

Internal IRB Screening

CPHS Office: The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

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
This is a New Project with Human Subjects' Contacts

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

December

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 11/05/2025 5:51 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 11/10/2025 9:06 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-172

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
The Chairs confirmed this project should be discussed in the December 5 full board meeting due to human subjects' contacts components.

Assign SME to study

John Schaeuble, PhD, MS

Enter the meeting date for this project

12/06/2025

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.

No answer provided.

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.