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 11/12/2024 7:13 PM ET by Trista Beard

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

October 2024 cycle.

_____HSC Full Board Project_____

A LOS from CCR is attached.
A DSL from USC is attached.

09/10/2024 • Sussan Atifeh • Internal

The researchers from USC are conducting a study called the Social Determinants of Health Survey among African American Men with Prostate Cancer (SDOHS) which is federally funded (National Institute of Minority Health and Health Disparities grant #U54MD010706.).
This study focuses on collecting and analyzing data about the health and social factors that affect African American men who have survived prostate cancer. The goal is to understand how factors like neighborhood, social isolation, financial strain, and stress contribute to prostate cancer outcomes. They will gather both clinical data and information directly from the patients through surveys.
The study is happening in Los Angeles County and aims to enroll up to 200 African American men who were treated for prostate cancer between 2017 and 2023.

Data Sources:
•Los Angeles Cancer Surveillance Program (CSP) and California Cancer Registry (CCR)—A LOS from CCR is attached.
•Surveys (conducted via REDCap, phone, mail) will collect social, behavioral, and demographic data from participants.

Data Linkages:
They will link clinical data from the CSP and CCR with the social and demographic information collected through the patient surveys. These linkages will help them understand how social determinants impact prostate cancer outcomes.

Important Points About the Project:

Purpose: The project aims to examine how social and health factors (like neighborhood conditions, stress, and financial strain) influence the health outcomes of African American men who have survived prostate cancer.
Procedures:
• Identification and Recruitment: Eligible patients will be identified by the CSP and contacted by the study team. Participants will receive an introductory letter, followed by phone calls, texts, or emails to complete a survey about their health and social environment.
• Survey Completion: Participants will complete a baseline questionnaire about their social and behavioral conditions, either online, via phone, or by mail.
• Clinical Data: will be collected from the CSP and CCR.
• Requested State Data: • Data from the California Cancer Registry (CCR) and Los Angeles Cancer Surveillance Program (CSP) will be used to gather clinical information about the participants, including diagnosis, treatment, PSA levels, cancer stage, and other clinical variables.
• Human Subjects Contacts: Researchers will contact up to 200 African American men via phone, email, mail, and text messages to recruit them and gather survey data.

09/10/2024 • Sussan Atifeh • Internal

Dear Researchers: Please check all pages of this application (scroll down to see the entire page), address the comment(s), and resubmit the application.
Thanks,

09/10/2024 • Sussan Atifeh • *Not* Internal • Resolved

Thank you Sussan for this summary

09/25/2024 • Jonni Johnson, PhD • Internal

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.

Chanita Hughes Halbert, PhD

Email: hughesha@usc.edu **Business:** (323) 442-1192

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

University of Southern California

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

Los Angeles

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.

CHH_CV_10.04.2023.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.

Trista Beard

Email: tbeard@usc.edu **Business:** (213) 284-5769

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.*

Ricky Bluthenthal, BA, MA, PhD

Email: ricky.bluthenthal@med.usc.edu **Business:** (323) 442-8236

OTHER RESEARCH STAFF

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

For approved studies, updates with to-be-named research staff will need to be submitted as an amendment for the study protocol to be listed as research staff on this project.

10/02/2024 • Jonni Johnson, PhD • *Not* Internal

Individuals are included in the budget but not named. An amendment to this protocol will be required if staff are added to the project who are not named here.

10/16/2024 • Laura Lund, MA • *Not* Internal

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.

Lihua Liu, PhD

Email: lihualiu@usc.edu **Business:** (323) 442-1636

Diana Morales, MPH

Email: dlm_191@usc.edu **Business:** (323) 442-7342

Evans Pope, MS

Email: Edpope@usc.edu **Business:** (615) 584-1497

Dayoung Bae, PhD

Email: dayoung@usc.edu **Business:** (323) 442-7200

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

False

Project Information

SUBMITTER

Application completed by:

Trista Beard
Email: tbeard@usc.edu **Business:** (213) 284-5769

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).

Social Determinants of Health Survey Among African American Prostate Cancer Survivors

PROJECT SITE

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

University of Southern California

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.

You have selected "HIPAA Waiver" in this section. Are you requesting HIPAA waiver from CPHS? Are the requested state datasets covered under HIPAA? Please check with the data-providing department(s) for your project and if the requested datasets are not covered under HIPAA, de-select "HIPAA waiver" in this section.

09/10/2024 • Sussan Atifeh • *Not* Internal • Resolved

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

Minimal Risk
Consent form

VULNERABLE POPULATIONS

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

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

Not applicable

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
National Institute of Minority Health and Health Disparities grant #U54MD010706.

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.

> Since this project involves with human subjects' contacts, it will be discussed in the upcoming full board meeting and is not eligible for an expedited review. Please select "Not applicable."
> Thanks.
>
> 09/10/2024 • Sussan Atifeh • *Not* Internal • Resolved

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. Please select 10/4/24 or a date after it within a few weeks. Thanks.
>
> 09/10/2024 • Sussan Atifeh • *Not* Internal • Resolved

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

12/09/2024

ANTICIPATED PROJECT END DATE

08/01/2025

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.

[Resolved in discussion on 10/30/2024] Researchers indicated there will be no database kept with state data and no intent to have study be prospective design.

[10/15/2024] In the previous submission, the study was not described as being prospective. In the resubmission, it is now described as prospective. What is the future event the study intends to track over time? ("SDOHS aims to prospectively collect, track, and analyze clinical and demographic data,"). Is the intent to have this be a type of pilot study for a future study?

The proposal of the annotated database needs to be described more. CCR data is state data and can only be used for pre-approved purposes and cannot be used without CPHS approval beyond what is described in/approved in the application. I am not clear on your description that the main aim of the study is to make a database.

Please also keep the language consistent throughout the application of the databases (e.g., recruiting database, consent/contact database, SDOH + CCR -annotated database?)

10/02/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

You state: We propose to create an annotated database by collecting and linking socio-demographic and clinical characteristics that are critical to patient care and outcomes among men with prostate cancer. This cohort data will be a valuable resource for cancer disparities research.

Are you referring to a database that will be used only for the study described in this research protocol or are you proposing to develop a database that will be used for other research not

described in this protocol?

If the latter, the creation of this database should be clearly described in the procedures section of this application. Please state what data will be retained, for how long, and who will have access to it in the future. In addition, participants will need to be made aware in the informed consent that this is one of the goals of the study. If any of the retained data originated from a state database (CCR/cancer registry), any further uses of the data beyond the specific use described in this protocol will need to be reviewed and approved by CPHS. Please describe how you will ensure that this happens.

10/15/2024 • Laura Lund, MA • *Not* Internal • Resolved

I agree with Dr. Johnson's question regarding the prospective nature of this study--is the plan to use the research/data described here in future studies?

10/15/2024 • Laura Lund, MA • *Not* Internal

Prostate cancer (PC) is the most common and second most lethal malignancy in U.S. men. Men from racial minority groups continue to experience poor health outcomes compared with non-minority men. The life expectancy for African American men (67.7 years) is substantially lower compared with white men (74.6 years). Reducing racial disparities in morbidity and mortality among minority men remains a national imperative. African American (AA) men experience both higher prostate cancer incidence rates and more adverse outcomes compared to their White counterparts. Prostate cancer outcomes are influenced not just by medical treatments but also by comorbidities, stress, and a range of social determinants of health, highlighting a pressing need for research to help understand how social risk factors (i.e., neighborhood deprivation, social isolation, negative life events, financial strain, and perceived stress) contribute to stress response and comorbidity, hereby contributing to disparities in prostate cancer patients. To accomplish this, we are launching the Social Determinants of Health Survey (SDOHS) among African American Men with Prostate Cancer. The SDOHS aims to collect and analyze clinical and demographic data, social and behavioral measures, patient-reported outcomes, and available clinical characteristics for African American prostate cancer survivors in the Norris Comprehensive Cancer Center catchment area (Los Angeles County). We propose to create an annotated data set for this study by collecting and linking socio-demographic and clinical characteristics that are critical to patient care and outcomes among men with prostate cancer. This cohort data will be a valuable resource for cancer disparities research. The end product will be a research report and/or article.
No identifiers will be retained after the data collection is complete. The data set will not be used for any other study. The data set will be retained only for analysis and publication of this research study.

MAJOR RESEARCH QUESTION

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

[Resolved in discussion on 10/30/2024] Researchers indicated there will be no database kept with state data and no intent to have study be prospective design.

With the study now being described as prospective, this research question seems like it should be modified. It is not just 'associations', but rather you describe how the prostate cancer prospectively predicts social outcomes. This is also a bit confusing with the study title being Social Determinants of Health, which would imply the reverse study design of having SD predict health outcomes.

10/12/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

What are the associations between socio-demographic and clinical characteristics that are critical to patient care and outcomes among men with prostate cancer?

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

Could you please describe the recruitment process in a bit more detail? Eligible persons are identified (please provide the estimated number - 200 is the study enrollment goal, but are 500, 1000, etc. being contacted for enrollment?)

How is it determined if phone calls/texts/emails are to be made? Are there tracking datasets that study staff employ or use to assist with who has responded, who has declined, etc.

Please clarify what "additional follow-up phone call may be conducted depending on the type of contact performed" means.

Is there an upper limit in the number of attempted contacts, wherein a "No Response" outcome from an eligible participant equates to a "Response of 'No'" - or are eligible participants contacted until they responded with 'yes' or 'no'?

09/22/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Are all persons who are on the study team that will be recruiting/contacting participants listed in the section above? The recruitment effort seems heavy for just 3 persons on study team.

Please also include the plan for analyses of data collected/linked in this study as well as the plan for publication or presentation of findings.

There are over 120 items collected in the survey, some responses about very personal feelings regarding medical diagnosis and stressful life events. Is the time estimate of 30 minutes accurate for setting the expectation? Do you anticipate for participants who would receive the survey over the phone or in person to take longer?

09/25/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Please clarify throughout application the usage of the ID - is this using the patient ID variable supplied in the CCR data request/clinical characteristics data -- or is this a separate ID generated within the purposes of this study to track recruitment/enrollment/completion?

[Resolved in discussion on 10/30/2024] Researchers indicated there will be no database kept with state data and no intent to have study be prospective design.

[Original 9/26/2024 comment] The separate issue of "create a high-quality database that can support future studies" - CPHS cannot approve collection and retainment of information as described for undisclosed/undescribed future studies. Elsewhere, the data is described as being destroyed after the completion of this project - what information would this database include?

09/26/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

[Note to Committee: Discussed with research team on 10/30/2024]-- Research team was considering modifying the SDOH section regarding victimization. Reviewers expressed concerns and researchers provided citation for clinical questionnaire. This issue is still pending further discussion by the Committee if additional modifications are not submitted.

Parts of the questionnaire are about serious and distressing information, regarding social isolation, financial uncertainty, and crime victimization. With an understanding that the study aims to examine how such experiences may relate to clinical characteristics, some questions do not seem appropriate - at least how currently phrased (e.g., asking if the participant was recent victim of a rape/violent assault and whether they view this as a good or bad experience), and is concerning. Are staff trained to handle potential distress in participants when conducting this via phone or in person? There needs to be additional/explicit resources provided to participants, supplying information on who to contact if the study procedures cause distress. Can you supply the literature on these or speak to the survey's questions validity? Perhaps use an existing questionnaire to gauge stressful experiences?

09/30/2024 • Jonni Johnson, PhD • *Not* Internal

[RESOLVED materials were submitted in latest submission] Please supply scripts you plan to use for contacting the participants in this section for calls, texts, emails. Clinical data abstraction, a clinical interview is mentioned, this needs to be supplied as well.

[RESOLVED] What does "incomplete survey data" mean? And how is this determined separate from a preference to not disclose information or skip a question? Is there a script for contacting persons with incomplete surveys?

09/30/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

[RESOLVED] Participants are consenting to be in the study, as outlined in the consent form. They are not consenting to be included in a database as outlined below. This is not described in the consent form of what is the intent to use or store the study data/CCR data.

[RESOLVED] Why is this now a prospective study?

[RESOLVED] What is the baseline health survey? Please include in materials for review. [Is this the same as the SDOH survey?]

No where in the recruitment letter or consent form is the option for RedCap described for participants to follow any link to complete the consent form and survey.

I am still unclear how it is to be determined that a survey is incomplete versus questions are being skipped, and whether this will impact whether the participants receive payment. Do you intend to pay a participant regardless if he decides to withdrawal mid-way? How do you plan to determine whether information is missing or deliberately omitted? Please also include the scripts you plan to use to re-contact participants about their missing information.

You have listed below that you are requesting data from 2017 or later. Then later that this is from 2017 to 2023. Please keep this language consistent.

Minimum data necessary wouldn't release the PHI of persons

who are eligible but either not contacted or declined. Is it possible to receive the contact/eligibility criteria only + patient_ID, then e.g., once the list of 200 participants is identified/whatever data delivery cadence is known that CSP provide just the CCR data for those 200?

10/02/2024 • Jonni Johnson, PhD • *Not* Internal

[RESOLVED in current submission - see note above regarding reviewer concern with SDOH regarding victimization.] Please describe the questionnaire in more detail. Are the items ("questions about loneliness, negative life events, financial strain and perceived stress") from an existing, valid, and reliable questionnaire?

[RESOLVED] Below the research coordinator is described as conducting/collecting responses to SDOH in-person or over phone - please clarify as this conflicts with other sections below with the TBD and phone script collecting this information as well.

10/12/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

You have stated that you plan to contact approximately 1000 individuals to achieve a final size of 200 cases and that you will stop when you reach 200. If questionnaires are returned to you in excess of n=200 what will you do with them?

10/15/2024 • Laura Lund, MA • *Not* Internal • Resolved

Please clarify your description of your recruitment procedures. There is some inconsistency and lack of complete information.

Please provide a maximum number of phone calls, text messages, and emails that potential participants will receive. At one point in the application you state that potential participants will receive an average of 6-8 phone calls, at another place in the application you state that participants will receive a maximum of 6-8 contacts. It is not clear if this contact maximum refers only to telephone calls, or if this maximum includes all contacts including text and email. Please clarify. (LL--this has been addressed in the current version.)

Will all participants who do not initially respond receive phone

calls, text messages, and emails? If not, how will you determine who receives phone calls/emails/texts?

You state that you will make additional calls depending on 'conversations with the patient and the likelihood of response.' What does this mean? If some participants will receive calls beyond the 6-8 average (or maximum, please see note above) that you anticipate, please
state the maximum number of calls and what, specifically, would trigger these additional calls. (LL--this has been addressed in the current version.)

Have scripts been provided for all recruitment phone calls, text messages, and emails? One phone script, one text message script, and one email script have been provided. Are these the only scripts that will be used? What about in the case of the 'additional' calls noted above? Is there a different script for follow up calls to people you have spoken with before, or will you say only what is in the script you have provided here? (LL--I believe this has been addressed in the current version.)

10/16/2024 • Laura Lund, MA • *Not* Internal

I agree with Dr. Johnson regarding the length of the survey and the administration time (30-40 minutes). Has this survey instrument been tested in a similar population to determine how long it takes people to complete?

10/16/2024 • Laura Lund, MA • *Not* Internal

I agree with Dr. Johnson's concerns regarding the highly sensitive nature of some of the items in the proposed survey instrument. My chief concerns are:

1) In the 'crime and legal matters' section you ask specifically about rape and violent victimization. Questions about rape should always be asked in a way that is sensitive to the individual's experience and respectful. In surveys, this type of question is usually immediately prefaced with warning language to let the person know that there will be questions about this very sensitive topic, that they might find it distressing, and that they can skip the question if they are uncomfortable. Asking the question in the way it is presented

here is not only insensitive it is potentially harmful. And asking rape survivors if their experience was 'good' is not acceptable. If questions about rape and violent victimization are important to your study I would request that they you use language that has been widely validated in other surveys to gather this information.

2) Q18 has a question with wording ...'difficulties piling up so high that you couldn't overcome them'... For people who answer fairly often or very often this could be triggering. How will you mitigate this? This questionnaire will be self-administered. Having staff who are trained to administer sensitive survey questions does not mitigate the problem for those who choose to complete the survey on paper or online. (LL--I believe this has been addressed in the current version.)

3) Q38. Why are you asking about race? Being AA is a requirement for this study. If you are not aware from the cancer registry data that a subject is AA then you will need a screener prior to informed consent to identify only AA individuals. It is not okay to subject individuals who are not eligible for this study to the informed consent process and the questionnaire. If you do not ascertain race until this very late point in the questionnaire there may be people who were burdened with answering these questions for a study it turns out they are not eligible for. What will you do if a person provides an answer to this question other than AA? (LL--this has been removed from the current version.)

4) Q39. How is where they were born relevant to the goals of this study? Given the population of interest (AA survivors of prostate cancer), why are you asking specifically about being born in Mexico, etc.? If knowing whether someone was born in the US or outside the US is relevant to the goals of the study then this should be a yes/no question. It is not clear at all why specific country of birth would be necessary for this study. (LL--This has been removed from the current version.)

The researchers have stated that the questions asked on this instrument are consistent with the kinds of questions that are typically asked in a clinical setting. Being asked and having to answer extremely sensitive questions on a survey is very different than having a conversation with a trusted medical

professional in a clinical setting.

10/16/2024 • Laura Lund, MA • *Not* Internal

You state: Every attempt will be made by study staff to ensure complete data collection. If a participant is unable to complete all questionnaires (by phone or online), a staff member will follow up with the participant to attempt to complete the questionnaires remotely (online or by phone or Zoom call). For those participants with incomplete survey data, (i.e., the subject began the survey but stopped in the middle) at least three attempts will be made to contact patients through different modalities (e.g., telephone, texting, email, mail), asking if they would like to complete their survey, or if they have chosen to stop at this point.

How are you defining 'incomplete'?

You have provided the participants with clear assurances that they can decline to answer any question and can stop the survey at any time. Given the highly sensitive nature of some of the questions, and the potential for those questions to be emotionally distressing for some individuals, I believe that you have to accept their non-response and choice to leave the questionnaire incomplete as their decision based on the assurances you have provided. Following up with individuals who have chosen not to complete the questionnaire because they are distressed or simply chose not to answer seems to be a violation of your assurances to them during the informed consent process.

If there is a plan to follow up with individuals whose questionnaires are incomplete that should be described completely here. How many phone calls, text messages, and emails do you propose to send? You state 'at least three'--what is the maximum? Please provide the scripts for all proposed follow up contacts.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

I agree with Dr. Johnson's point regarding what needs to happen for individuals to receive the $25 gift card. Please clarify in the protocol and the consent form what participants need to do to get the $25. Do they need to complete the

whole questionnaire? What if they only partially complete it? (LL--I believe that this has been addressed in the current version of the consent form.)

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

I agree with Dr. Johnson's comment regarding concerns about minimum data necessary. It would appear that only the minimum amount of information necessary for recruitment should be released until individuals have agreed to participate in the study. Then the remainder of the cancer registry information would be released only for study participants. Is this what is planned? Also, is it possible to recruit in batches so that only PHI on the minimum number of individuals necessary to achieve the n=200 sample size is released?

10/16/2024 • Laura Lund, MA • *Not* Internal

Please describe your consenting procedures for all three modalities for questionnaire administration--paper, online, and telephone. Elsewhere you have stated that you are asking for a waiver of written informed consent. It is not clear why a waiver of written informed consent would be necessary for individuals returning paper copies of the questionnaire--the signed consent form can be returned in the envelope with the questionnaire. Similarly, persons completing the questionnaire online can read and sign the consent form prior to beginning the survey. In the case of phone participants a waiver of written informed consent might be appropriate, but they must receive informed consent equivalent to the consent for the other two modalities. The waiver just means that the consent process does not require a written signature, it is not a waiver of the informed consent itself. If it is appropriate participants can provide verbal consent rather than signing a written document. The process for consenting individuals by phone has not been clearly described. The text scripts provided for contacting individuals to administer the survey by phone are not adequate as they do not meet the elements of informed consent and they do not provide the necessary information about the study that participants in the other two modalities will receive. The introduction at the beginning of the phone survey that has been provided does not contain the elements of informed consent. Please address this.

10/16/2024 • Laura Lund, MA • *Not* Internal

Please include a CCR brochure in the packet to be mailed to participants. A CCR brochure has been provided as an exhibit elsewhere in this application but does not appear to be included in the mailing packet.

10/16/2024 • Laura Lund, MA • *Not* Internal

You state you will make a phone contact two weeks after the mailing. Does this refer to the 6-8 call maximum that you describe elsewhere? Where do the text messages and email fit in?

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

You state that you will send a new packet of materials four weeks after the initial mailing. What will be in this packet? Will there be a different letter? Will there be any additional follow up after this mailing?

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

You have provided a survey that appears to be intended for in person or phone administration. Please provide the final version of the survey that you plan to include in the packet to be mailed to participants.

10/16/2024 • Laura Lund, MA • *Not* Internal

What will you do if you receive a questionnaire mailed back without a consent form?

10/16/2024 • Laura Lund, MA • *Not* Internal

Based on description below in Subject identification, CSP will be creating Study IDs.

Please clarify when the PHI data will be sent for consented participants, it is somewhat unclear if the PHI is sent for all 1000, regardless if they consent to be in the study. Could you please clarify to meet minimum data necessary requirements:

1. CSP would pull the 1000 eligible participants and required PII needed for recruitment only and assigned the Study ID.
2. After consent, the 200 participants Study IDs are sent to CSP,
3. and then CSP sends the additional prostate cancer/health data for those 200 individuals.

Under Recruitment: "Once a subject agrees to participate, they will be issued a Study ID and their demographic and tumor information from the registry will be entered into the study database that, which will house the SDOH survey." - please resolve this inconsistency with when Study ID is being assigned/by whom.

Additional minor adjustments: - language below still lists "patients who consents to be included in database" - please modify to be consistent with rest of proposal and not use of database.

"We will request all eligible AA survivors diagnosed in 2017 or later." Please change end year to be consistent with application (i.e., 2017-2023).

11/06/2024 • Jonni Johnson, PhD • *Not* Internal

STUDY PROCEDUERES: SDOH Survey of African American Men with Prostate Cancer

There will be two major aspects to creating the study cohort: patient SDOH surveys and clinical characteristics. The first step is to identify and consent those that would be included in the study. Each potential subject identified by Los Angeles Cancer Surveillance Program (CSP) will be given a Study_ID. Study ID will be created by CSP and they will retain the key to contact information and patients' clinical variables. Potential subjects will be contacted by mail, and then by phone, and then by email and invited to complete an SDOH survey. Patients who consent to participate will be asked to complete questionnaires. Clinical characteristics will be collected from the associated cancer registry dataset provided by the Los Angeles Cancer Surveillance Program (CSP) (e.g., diagnosis, PSA, stage of disease at diagnosis, comorbidities), after subjects consent to participate. Through utilizing the population-based cancer registry data with clinical characteristics and combined with patient self-reported life conditions and experiences collected through the SDOH survey, we will create a high-quality data set for this project.

1 Subject Identification
Eligible patients will be identified by CSP, based on the eligibility criteria (listed below). CSP has provided an estimate of approximately 200 eligible African American men per year in Los Angeles (LA) County that met the study eligibility criteria. We will request all eligible AA survivors diagnosed from 2017 to 2023. We will use the contact information provided by CSP to contact all eligible survivors and invite them to participate in the study and complete the survey, until we research our enrollment goal of 200

participants.
Adult African American men diagnosed with prostate cancer, in LA County, who were treated with radical prostatectomy from 2017 through 2023. CSP will identify cases and will give each potential subject a study ID.

Eligible participants will be:
1. African American Men 18 years of age or older.
2. Men with a diagnosis of prostate cancer who have completed a radical prostatectomy.
3. Prior or concurrent participation in other clinical trials is allowed.
4. Reside in Los Angeles (LA) County.

2 Recruitment
The study team will not use any registry ID numbers in the study. A separate Study ID will be generated for each eligible person who will be invited to participate in the survey.

A recruitment contact database will be developed by the study team. The recruitment database will be stored in REDCap and will track contact activities from sending contact letters to follow-up by phone, text, and email, as well as contact outcomes. The study team will send eligible participants an introductory letter describing the study and requesting participation, and will include instructions for completing the SDOH survey online via unique REDCap link or by phone with study staff. Study staff will make recruitment phone calls to eligible cases 2 weeks after the initial mailing. A follow-up email and text will be sent to anyone we could not reach by phone. The average number of calls per patient will range from 6-8. Phone calls will be staggered throughout the week, nights, and weekends. Text and email invitations will also be utilized, after the first phone call attempt. A maximum of 8 contact attempts (incl. phone, email and text) will be made to contact potential participants about study participation, after the mailer, over a 60-day period. Once the study team has reached 8 contact attempts, over 60 days, the participant will be marked as “No response” and contact will cease.

The recruitment database and the study database will be linked only by Study ID. Once a subject consents to join the study, their SDOH survey will be entered into the study database. Demographic and tumor information will be requested form CSP only for those who men who consented to the study.

This study will use evidence-based strategies from Dr. Hughes-Halbert's previous research to complete recruitment (Halbert, Jefferson, Allen, et al. Racial Differences in Patient Portal Activation and Research Enrollment Among Patients With Prostate Cancer. JCO Clin Cancer Inform. 2021 Jun;5:768-774. PMID: 34328797; Halbert, Love, Mayes, et al. Retention of African American women in cancer genetics research. Am J Med Genet A. 2008 Jan 15;146A(2):166-73. PMID: 18076114.). Based on this experience, we estimate that about 20% of patients will be contacted and agree to participate in the study; therefore, we will contact 1000 patients to enroll a sample of 200 patients.

Contact protocols from Dr. Hughes-Halbert's previous research (referenced above) will be used to inform the number of contacts that will be made to potential participants. Specifically, a maximum of 8 attempts will be made over a 60-day period to complete study enrollment.

Additional follow-up phone calls are a component of the contact protocols using in Dr. Hughes-Halbert's previous research (referenced above); as indicated in the comment above, a maximum of 8 attempts will be made to potential participants to ensure they received the study materials and answer any questions they have about participating in the research.

3 The Survey
The informed consent form will be provided at the beginning of the REDCap survey. We are asking for a waiver of written consent for phone contact; the patient will be read an abbreviated version of the consent form and will be asked to give verbal assent to participate in the survey via phone.

Following informed consent, participants may complete the SDOH survey online through REDCap. Participants can complete the electronic questionnaire at home on their personal computer or the research coordinator can read the questions aloud (by phone) and enter their responses in the REDCap study database.

The SDOH survey that will be completed as part of this survey has been used in Dr. Hughes-Halbert's previous research. The survey administration time to about 40 minutes.

Validated instruments and questions that are routinely asked as part of cancer care delivery and/or epidemiological research will be administered in the survey. For instance, the Functional Assessment of Cancer Therapy - General Short Form has been well-validated in diverse cancer patient populations and is administered as part of cancer clinical trials to measure patient reported outcomes. Similarly, the Loneliness Scale (Hughes, Waite, Hawkley, et al. A short scale for measuring loneliness in large surveys: Results from two population-based studies. Research on aging. 2004 Nov;26(6):655-72) validated as part of epidemiological studies and has been used in our previous research to measure social isolation among African American cancer patients. Lastly, questions about loneliness, negative life events, financial strain and perceived stress have been administered to prostate cancer patients as part of Dr. Hughes-Halbert's previous research in cancer disparities and minority men's health. All question batteries in the survey are drawn from validated scales*: The Life Events Questionnaire (LEQ; Norbeck, 1984; Sarason, Johnson, & Siegel, 1978) is a validated measure that is being used to measure life events across health, work, residence, and financial domains. The Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983) is being used to measure perceived stress and the short forms of the Loneliness Scale (M. E. Hughes, Waite, Hawkley, & Cacioppo, 2004) and Interpersonal Support Evaluation List (ISEL; Payne et al., 2012) are being used to measure social isolation and support, respectively. Financial strain is being measured using a validated Likert-style item (Pearlin et al., 1981) that asks participants if they have some, just enough, or not enough money left over at the end of the

month.

4 Clinical Data Abstraction
Clinical variables will be abstracted from the CSP case report and recorded in the study database. Clinical variables will only be requested from CSP for those who consented to join the study.

5 Data Collection
Every attempt will be made by study staff to ensure complete data collection. If a participant is unable to complete the questionnaire (by phone, due to a time conflict, and the participant asks for a call back at a later time), a staff member will follow up with the participant to attempt to complete the questionnaire by phone. Any surveys submitted on REDCap, will be considered complete, as participants have the right to skip questions or stop any time they choose.

6 Database and Data Protection
The PI will oversee data management, processing, and analytic services for this project.
1. The original data collection will be kept REDCap.
2. All electronic participant data, including files and databases, will be stored on HIPAA compliant servers configured and maintained by USC.
3. Access to servers is restricted to the USC network, which requires two-factor authentication.
4. Any study communications made by e-mail, among the study team, will use assigned study ID numbers (SIDs) only and never include names or any other personal information.
5. All study data will use SIDs only. The contact list provided by CSP and the recruitment database will contain names. A key of study IDs will be kept separate from the study (survey) data. Once we have completed survey collection, we will pull the SIDs from the key and request the clinical variables for those men who enrolled in the study. No clinical variables will be shared for men who did not enroll in the study.
6. Only study personnel actively working on the projects will have access to data.

7 Data Analysis
The data analysis is designed to describe social determinants of quality of the life following prostate cancer diagnosis and treatment among African American men. To do this, descriptive statistics will be generated first to characterize socioeconomic factors (e.g., education, employment status), clinical factors (e.g., state of disease, PSA at diagnosis), social characteristics and experiences (e.g., perceived stress), and quality of life. Second, bivariate analyses will be conducted to identify socioeconomic, clinical, and social factors that are associated with quality of life outcomes. Next, multivariate regression analyses will be conducted to identify factors having significant independent associations with quality of life outcomes.

8 Study Team
The study team includes the appropriate expertise to complete study enrollment, data collection, and quality assurance and monitoring. All study personnel have completed Human Subjects training on CITIProgram.org and

are trained to ask sensitive questions in an appropriate manner. Collectively, our team has more than 20+ years of experience conducting cancer health disparities with African American patients. In addition, many of the items included in this survey have been administered to more than 1000 patients and community residents as part of Dr. Hughes-Halbert's previous and ongoing research.

*Citations for validated measures used in SDOH Survey:
Norbeck, J. S. (1984). Modification of life event questionnaires for use with female respondents. Research in Nursing & Health, 7, 61–71. http://dx.doi.org/10.1002/nur.4770070110
Sarason, I. G., Johnson, J. H., & Siegel, J. M. (1978). Assessing the impact of life changes: Development of the Life Experiences Survey. Journal of Consulting and Clinical Psychology, 46, 932–946. http://dx.doi.org/10.1037/0022-006X.46.5.932
Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. Journal of Health and Social Behavior, 24, 385–396. http://dx.doi.org/10.2307/2136404
Hughes, M. E., Waite, L. J., Hawkley, L. C., & Cacioppo, J. T. (2004). A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. Research on Aging, 26, 655– 672. http://dx.doi.org/10.1177/0164027504268574
Payne, T. J., Andrew, M., Butler, K. R., Wyatt, S. B., Dubbert, P. M., & Mosley, T. H. (2012). Psychometric evaluation of the interpersonal support evaluation list-short form in the ARIC study cohort. Sage Open, 2, 1– 8.
Pearlin LI, Menaghan EG, Lieberman MA, Mullan JT. The stress process. Journal of Health and Social behavior. 1981 Dec 1:337-56.

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.

ICF for SDOH survey of AA ProCa survivors_revised 11.8.24.docx	Consent Form
USC Health Equity Project 1_SDOH Survey_11.8.24.doc	Instruments
CCR reporting info for patients_English-in-color.pdf	Misc/Other
Recruitment Letter for SDOH survey 11.8.24.docx	Recruitment Materials

Deleted Attachments: 5 (Most Recent: Recruitment Letter for SDOH survey 11.8.24.docx on 11/12/2024 7:11 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.

Please in the right column enter:
Los Angeles County Cancer Surveillance Program (CSP), California Cancer Registry (CCR)

09/10/2024 • Sussan Atifeh • *Not* Internal • Resolved

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	Los Angeles County Cancer Surveillance Program (CSP), California Cancer Registry (CCR)

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.

A few clarifications for study eligibility:

Please include number of estimated people you plan to contact, not just enroll in the study.

How was the 200 number determined?

The CCR database has 5 race indicator variables - are individuals eligible if African American appears in any of these 5 race fields or are individuals eligible if African American is the only race field indicator value?

09/22/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Thank you for providing the estimate recruitment and study N estimates.

Will participants be denied participation if they are 201 person or higher? Please include statement as part of eligibility description.

10/02/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

I agree with Dr. Johnson--please describe what will happen if your recruitment procedures result in n>200.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

Adult African American men diagnosed with prostate cancer, in LA County, who were treated with radical prostatectomy from 2017 through 2023. LA CSP will identify cases and will give each potential subject a study ID.

Eligible participants will be:
1. African American Men 18 years of age or older.
2. Men with a diagnosis of prostate cancer who have completed a radical prostatectomy.
3. Prior or concurrent participation in other clinical trials is allowed.
4. Reside in LA County.

LA CSP has provided an estimate of approximately 1000 men in LA County that may be eligible. Our enrollment goal 200 men who will complete an

SDOH survey study. The goal of capturing surveys from 200 men will allow us to have power to detect differences among clinical and socioeconomic factors. Once we hit our enrollment goal, we will stop recruitment efforts. If we receive surveys beyond the 200, we will include them in the dataset for analysis.

Men will be eligible if they include African American or Black in any of the 5 race indicator variables.

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.

[RESOLVED - study is not prospective in most recent submission description] You are not requesting future data for the time periods from CCR, does this timeline need to be adjusted if this is now a prospective study? Or is the CCR data predicting current SDOH data?

Is the baseline questionnaire the same as the SDOH survey? Please use consistent language throughout the application for your datasets and materials: New names for the same materials just look like new materials.

[RESOLVED] Some variables are described as clinical characteristics needed to define differences within the study - please include this as part of your study plan. Please also include description of the social deprivation index score that the variables are cited as needed to compute.

Is patient ID needed? Why is the main ID with CCR data needed if a study ID is going to be created? (---this variable may or may not be needed depending on the finalized data sharing 10/12/2024)

[RESOLVED] What are the two attachments? Are these not from the same database, but the approved xlsx has more variables? Please only include the variables that you are requesting. If these are from separate databases but presumably the same variables from same variable names, is the duplication needed?

10/02/2024 • Jonni Johnson, PhD • *Not* Internal

In description above, CSP is to create a study ID that is used to identify participants and link with recruiting information and additional PHI for consented persons. The below description however still is requesting Patient_ID and the attached data request still have Patient_ID. Please confirm if Study_ID is different from Patient_ID and modify data request form if

Patient_ID is no longer being requested.

11/06/2024 • Jonni Johnson, PhD • *Not* Internal

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.

LA County Cancer Surveillance Program (CSP) will search the CCR for cases of prostate cancer among African American men diagnosed between 2017 and 2023. Men who are living, and were treated with radical prostatectomy will be added to a patient contact database. The study team will send eligible participants an introductory letter describing the study and requesting participation, and provide instructions for completing the questionnaire online via REDCap link or by phone with study staff. Study staff will make recruitment phone calls to eligible cases 2 weeks after the initial mailing, and follow-up with email and text if we do not make contact with a subject by phone. The average number of calls per patient will range from 6-8. Phone calls will be staggered throughout the week, nights, and weekends. Text and email invitations will also be utilized, after the first phone call attempt. A maximum of 8 contact attempts (incl. phone, email and text) will be made to contact potential participants about study participation, after the mailer, over a 60-day period. Once the study team has reached 8 contact attempts, over 60 days, the participant will be marked as "No response" and contact will cease.
LACSP will provide contact information: name, address, email, phone number.
LACSP will assign a study ID to each potential subject and will retain the key linking Study ID to Patient ID.
Clinical characteristics will be requested for those men who enroll in the study. Clinical variables are attached here.
The list of requested variables has been approved by CCR.

Data Protection:
The PI will oversee data management, processing, and analytic services for this project.
1. The original data collection will be kept REDCap.
2. All electronic participant data, including files and databases, will be stored on HIPAA compliant servers configured and maintained by USC.
3. Access to servers is restricted to the USC network, which requires two-factor authentication.
4. Any study communications made by e-mail, among the study team, will use assigned study ID numbers (SIDs) only and never include names or any other personal information.
5. All study data will use SIDs only. The contact list provided by CSP and the recruitment database will contain names. A key of study IDs will be kept separate from the study (survey) data. Once we have completed survey collection, we will pull the SIDs from the key and request the clinical

variables for those men who enrolled in the study. No clinical variables will be shared for men who did not enroll in the study.
6. Only study personnel actively working on the projects will have access to data.

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.

Approved_Variable List_for SDOHS of AA PrCa survivors in LAC_11.8.24.xlsx	List of Variables

Deleted Attachments: 3 (Most Recent: Approved Variable List for SDOHS of AA PrCa survivors in LAC_11.8.24.xlsx on 11/08/2024 8:14 PM ET)

RATIONALE

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

Precision medicine is defined as "an emerging approach for disease treatment and prevention that takes into account individual variability in environment, lifestyle, and genes for each person". However, the absence of empirical data on the interactive effects of these factors may limit the development of effective strategies for precision medicine and the dissemination and implementation of these approaches in both clinical and public health settings. Understanding the interplay between the lived experiences and social drivers of health among AA men with prostate cancer can guide more holistic approaches to treatment and support.

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.)?

[RESOLVED] The recruitment letter mentions completing an 'interest survey'. Please attach a copy of this interest survey for review. Do all persons complete this interest survey or just those using the link provided in the recruitment letter?

Similar to consent form - the recruitment letter reads at 11th grade level. Please revise this down to 8th grade reading level.

09/26/2024 • Jonni Johnson, PhD • *Not* Internal

Recruitment form has improved - grade level is now at 10, please modify down to 8 if possible. Explanation of the CCR brochure or reference to in recruitment letter is needed. Please include that they will be asked about their finances and crime victimization in recruitment letter as well as consent form.

The scripts are inconsistent with each other about why participants are being contacted, purpose of the research, and workflow (e.g., text option has different options and results than listed for phone - confirmation of receiving previous letter, confirmation contact information is accurate).

On phone script, you offer that participants will be offered to complete study at that time over the phone. The TBD callers though are listed as for recruitment only, and would be collecting the SDOH responses. Please clarify these persons roles and confirm that they will have appropriate training to collect responses that are sensitive and how to handle adverse responses.

10/02/2024 • Jonni Johnson, PhD • *Not* Internal

Recruitment form, Email/text scripts, and/or consent should include information about completing the consenting

process/SDOH responses via REDCap

10/12/2024 • Jonni Johnson, PhD • *Not* Internal

The recruitment letter lacks critical information to guide the participant through the process of how to participate in the study. There should be information on what to do if they choose to participate by returning the paper questionnaire (tell them they need to read all materials thoroughly, they need to read and sign the consent form before proceeding with the questionnaire, they should contact a member of the study team if they have any questions about the consent form or the questionnaire, they should return the completed consent form and the questionnaire in the return envelope, etc. Similarly for what to do if they want to participate online or by phone.)

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

I agree with Dr. Johnson's comment regarding informing them about the sensitive nature and the specific content of the survey in the recruitment letter. If I was a potential participant receiving this letter I would expect that I was expressing interest in participating in a survey that was only going to ask me about health and demographics.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

The introductory letter should provide a person's name (not just a phone number and email) to request opt out. (LL--this has been addressed in the current version.)

Script for 1st phone contact--

--Is this the only script that will be used when contacting individuals by phone? In the procedures there is a statement about multiple phone calls based on answers potential subjects may give. Please provide all phone scripts.

--In order to avoid inadvertently disclosing confidential medical information to other household members, the introduction to this script should carefully ask to speak to the correct person, instead of assuming that the correct person is already on the line.

--The script states that the participant will receive a $25 incentive. It should clearly state what the incentive is for, for example, 'you will receive a $25 gift card if you complete the survey', or whatever the requirement is.

--the script does not offer any opportunity for phone participants to complete the informed consent. Phone participants must complete an informed consent before the survey starts.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

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

Registry staff at the LA County Cancer Surveillance Program (CSP) will identify eligible cases in the cancer registry database. A patient contact database will be provided to the study team. The study team will send eligible participants an introductory letter describing the study and requesting participation and providing instructions for completing the survey online via REDCap link or by phone with study staff. Study staff will make recruitment phone calls to eligible cases 2 weeks after the initial mailing. The average number of calls per patient will range from 6-8, however, additional follow-up phone calls may be conducted depending on conversations with the patient, and likelihood of response. Phone calls will be staggered throughout the week, nights, and weekends. Text and email invitations will also be utilized, if we are not able to reach the person by phone.

Attach copies of all recruitment materials.

CCR reporting info for patients_English-in-color.pdf	Recruitment Materials
Recruitment Letter for SDOH survey 11.8.24.docx	Recruitment Materials
SDOH Phone Email and Text Scripts_11.8.24.docx	Recruitment Materials

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SCREENING

Will subjects be screened prior to entry into the research?

Please modify this entry- you have eligibility criteria listed for the study

09/30/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

You state: Men will be eligible if they include African American or Black in any of the 5 race indicator variables.

This should be determined prior to administering informed consent and beginning the survey. Where is this information coming from? Is it from CCR? If it is self-report individuals should be screened prior to informed consent and questionnaire administration so that ineligible individuals are not subjected to survey burden and risk.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

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.
LA CSP will complete the screening before providing a recruitment list.

Adult African American men diagnosed with prostate cancer, in LA County, who were treated with radical prostatectomy from 2017 through 2023. LA CSP will identify cases and will give each potential subject a study ID.

Eligible participants will be:
1. African American Men 18 years of age or older.
2. Men with a diagnosis of prostate cancer who have completed a radical prostatectomy.
3. Prior or concurrent participation in other clinical trials is allowed.
4. Reside in LA County.

LA CSP has provided an estimate of approximately 1000 men in LA County that may be eligible. Our enrollment goal 200 men who will complete an SDOH survey study.

Men will be eligible if they include African American or Black in any of the 5 race indicator variables. LA CSP will complete the screening based on

eligibility criteria.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
$25

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.

> After reading through the list of questions, I, myself, took more than 30 minutes to read through - I would recommend this time estimate be increased to set expectations for the participants about time investment/commitment.
>
> 09/25/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

> This time adjustment is better, but I still do not think this is a reasonably amount of time to read, think about, and respond to more than 100 items on a questionnaire. You mentioned that this questionnaire has been used in previous studies - how long did those sessions last? Or if questionnaire has been completed previously with RedCap in other study, what was the study completion/duration?
>
> 10/02/2024 • Jonni Johnson, PhD • Internal

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.

This is a 1 year study. Each subject will be involved for about 40 minutes and will complete 1 survey.

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.

What is the plan to offer participants assistance if feeling distressed or overwhelmed with questions? Are study staff trained to handle or refer participants to available resources?

09/25/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Some of the questionnaire items seem greater risk than mild discomfort, particularly if an individual has behavior or mental health issues. Please add some community or available resources available for participants, add additional clarification about withdrawing from the study at any time if too distressed, skipping questions. Please include description of plan of dealing with potential distress in participants.

09/30/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

The questionnaire contents has potential to surpass minimal risks. The risk of a crime victim being asked if their rape was a 'good' or 'bad' experience does not meet the federal definition of minimal risks for participants: See 45 CFR 46.102(j). These are incredibly sensitive topics that are not the type of information that might be gathered in general public interaction or routine physical/psychological screenings.

[RESOLVED: Research team has added portions to consents and prior to SDOH questions including available resources] Participants should be provided with the information of the resources regardless of whether they express/verbalize to staff that they are presently feeling distressed. This is needed particularly if participants feel distressed immediately after the session.

It is relieving to hear that the questions have not previously resulted in adverse emotional responses, but that doesn't make the questions themselves less risky. The intent is to provide protection for the participants that will be in this study, who would still be at risk of experiencing distress

despite other persons not reporting distress previously.

[RESOLVED] Please provide the specific training that the research staff and the to-be-named research staff have/will have completed to speak with potential victims of crime about their experiences for phone and in-person interviews with the questionnaire.

10/02/2024 • Jonni Johnson, PhD • *Not* Internal

I agree with Dr. Johnson's comment that the questionnaire has the potential to make this a greater than minimal risk study if the highly sensitive questions regarding rape and violent victimization are not modified.

10/16/2024 • Laura Lund, MA • *Not* Internal

I agree with Dr. Johnson's comment that participants need to be provided with resources even if they do not let study staff know that they are feeling distressed by some of the potentially triggering questions. How will this be accomplished for individuals who choose to complete the survey on paper or online?

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

I agree with Dr. Johnson's comment: It is relieving to hear that the questions have not previously resulted in adverse emotional responses, but that doesn't make the questions themselves less risky. The intent is to provide protection for the participants that will be in this study, who would still be at risk of experiencing distress despite other persons not reporting distress previously.

Also please note, just because individuals did not report adverse emotional responses does not mean that they did not occur.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

As described previously, the study team includes the appropriate expertise needed to complete study enrollment,, data collection, and quality assurance and monitoring. Collectively, our team has more than 20+ years of experience conducting cancer health disparities research with African American patients. In addition, many of the items included in this survey have been administered to more than 1000 patients and community residents as part of Dr. Hughes-Halbert's previous and ongoing research without reports of adverse emotional responses. Study staff are trained to

refer participants to available resources, and also have significant supervision in administering the survey as part of our quality assurance and data integrity procedures. It is also important to note that the risks of completing the survey (and study enrollment) are minimal and may include the following:

Risks associated with this study may include some mild discomfort with answering survey questions about personal health and personal factors that impact one's life. There is minimal risk that subjects will experience distress, but if distressed, subjects can stop the survey at any time. Questions in the survey are typical of those asked in healthcare delivery settings. Participants will complete the survey on paper (via mailer), on the phone or online. Patients may decline to answer any question (any question may be skipped). Staff are trained to ask sensitive questions about a person's health and lived experience. Participants who are experiencing distress related to their cancer diagnosis will be referred to NCI Cancer Helpline at 1-800-4-CANCER (1-800-422-6237 LiveHelp Online Chat).

We will refer any subjects who express that they are distressed by the survey questions to the LA County Mental Health Services 24/7 Help Line at (800) 854-7771. Any subject who expresses that they do not want to continue will be allowed to end their participation and we will mark their survey as completed. We have added trigger warnings about sensitive questions into the survey at the beginning and before the Life Events Scale and Perceived Stress Scale, and included the Mental Health Hotline number in both places, as well as a reminder that subjects may skip any question they do not want to answer.

There is a risk of loss of confidentiality of the information that is used in this study. The institution and the investigative team for this study will take every precaution to ensure that personal information is kept confidential during this study.

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.

> See note above. All participants should receive information on what resources are available if feeling distress during or after the study procedures.
>
> Update 11/6/2024: Have this section updated to include the additional resources provided in consent process.
>
> 10/03/2024 • Jonni Johnson, PhD • *Not* Internal

No services will be provided.
We will refer any subjects who express that they are distressed by the survey questions to the LA County Mental Health Services 24/7 Help Line at (800) 854-7771. Any subject who expresses that they do not want to continue will be allowed to end their participation and we will mark their survey as completed.

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.

Please see note above about meeting minimal risk definitions for study procedures. If you intend to keep the questionnaire format as it is, this section will need to be modified.

10/12/2024 • Jonni Johnson, PhD • *Not* Internal

The survey study is minimal risk. There are no less risky methods available. We have added trigger warnings about sensitive questions into the survey at the beginning and before the Life Events Scale and Perceived Stress Scale, and included the Mental Health Hotline number in both places, as well as a reminder that subjects may skip any question they do not want to answer.

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.

There will be no direct benefit to subjects from participating in this study. However, it is hoped that the information gained from the study will help develop our understanding of social risk factors and their influence on cancer survival and outcomes.

JUSTIFICATION OF RISKS

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

The survey study is minimal risk, and the knowledge gained may improve our understanding of the relationship between social risk factors and cancer outcomes among African American men with prostate cancer.

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 add here that you are requesting medical ID/Patient_ID as part of data request and several dates (Date of birth, date of Dx, surgery date)

[updated 10/16/2024] Patient_ID may help facilitate data linkage if the recruitment method is modified - just flagging this section for now. If patient_ID is put back in, then this section will need to have that listed as well.

[updated 11/6/2024] Patient_ID is still listed as being a requested variable, but procedures describe a Study_ID that is not Patient_ID. Patient_ID does not need to be listed here if ultimately not requested and CSP assigned alternative Study_ID

09/25/2024 • Jonni Johnson, PhD • *Not* Internal

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

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 on the study team are required to have CITI training in human subjects research and HIPAA. Survey data will be stored in REDCap. Staff will not be required to sign a confidentiality statement.

STAFF VETTING PROCEDURES

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

Staff at USC are vetted through background checks. Only study personnel with certified research training will have access to study data.

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.

CPHS_LOS_Hughes-Halbert, C.docx.pdf Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

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

All eligible database, recruiting database, and study database are to be held in REDCap?

10/02/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

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.

All data will be stored on REDCap and only study personnel will have access to the study data. The PI will ensure that data will not be re-used or shared with any unauthorized persons.
Contact list from CSP will be stored in REDCAP, as well as the recruitment database and the study database.

CONFIDENTIALITY OF PUBLISHED DATA

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

Please provide additional information for how this will be carried out in analyses and reporting/presentations

09/25/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

All data will be de-identified prior to analysis and reporting. No published reports or papers will include identifiable data.
The data analysis is designed to describe social determinants of quality of the life following prostate cancer diagnosis and treatment among African American men. To do this, descriptive statistics will be generated first to characterize socioeconomic factors (e.g., education, employment status), clinical factors (e.g., state of disease, PSA at diagnosis), social characteristics and experiences (e.g., perceived stress), and quality of life. Second, bivariate analyses will be conducted to identify socioeconomic, clinical, and social factors that are associated with quality of life outcomes. Next, multivariate regression analyses will be conducted to identify factors having significant independent associations with quality of life outcomes.

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?

Who is the CSP Co-I?

10/12/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

We are requesting the minimum necessary data, for AA prostate cancer survivors in LA County, diagnosed between 2017 and 2023. Clinical variables are requested to compare against the social risk variables to be obtained by SDOH survey.
Clinical variables include those listed below.
Cancer History and Clinical Characteristics: Clinical characteristics will be extracted from the CSP case report by trained study coordinators, and will include clinicopathological data (e.g., Gleason score, Grade group, PSA level, pathological stage), and comorbidities (Charlson score).
Cancer Registry Data: Cancer diagnosis and treatment information will be obtained through linkage with the California Cancer Registry (facilitated by the LACSP Director, Lihua Liu). Data to be extracted will include demographics, residence at diagnosis, cancer diagnosis dates, tumor histology and staging, comorbidities at diagnosis, dates and types of treatments received.

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.

Please clarify -- If participants are being emailed the form to complete - how will they know their own Patient ID number? Or is point 4 only regarding email communication between study staff?

09/26/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Please clarify -- There appear to be at least three dataset: 1. An original dataset that would contain PHI from CCR/list of eligible persons, 2. a recruiting dataset tracking outcome of contact (yes, decline, no response, number of attempts to contact, form in which contact was attempted), and then a linked dataset that will be the CCR/PHI + SDOH. If this is accurate, please clarify #5 below as names will be required for first two.

[Update 11/6/2024] Below describes procedures in line with minimum data necessary please make Database Description and Procedure sections above mirror the description in this section.

10/12/2024 • Jonni Johnson, PhD • *Not* Internal

The PI will oversee data management, processing, and analytic services for this project.
1. The original data collection will be kept REDCap.
2. All electronic participant data, including files and databases, will be stored on HIPAA compliant servers configured and maintained by USC.
3. Access to servers is restricted to the USC network, which requires two-factor authentication.
4. Any study communications made by e-mail, among the study team, will use assigned study ID numbers (SIDs) only and never include names or any other personal information.
5. All study data will use SIDs only. The contact list provided by CSP and the recruitment database will contain names. A key of study IDs will be kept separate from the study (survey) data. Once we have completed survey collection, we will pull the SIDs from the key and request the clinical variables for those men who enrolled in the study. No clinical variables will be shared for men who did not enroll in the study.
6. Only study personnel actively working on the projects will have access to data.

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.

Please describe this method in additional detail for plan against small cell size for publication of project

09/26/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

All data will be de-identified for analysis and reporting. No published reports or papers will include identifiable data.

The Data Suppression Rule of 11 will be used in statistical reporting, as it is commonly used to protect the privacy and confidentiality of individuals in small datasets. When a dataset contains fewer than 11 individuals in a given category (e.g., age, gender, diagnosis), the data related to that category is suppressed or not reported.
Data suppression ensures that personal information cannot be inferred by anyone analyzing the dataset, preventing breaches of confidentiality.

LINKAGES

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

> Please check your response in this section and if necessary change it to "Yes." Thanks,
>
> 09/10/2024 • Sussan Atifeh • *Not* Internal

> Please change response to yes. You are linking CCR data with your SDOH data. Additionally, there is now linkage between the study database and the recruiting database.
>
> 10/02/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

> Please change your response to yes. Your stated plan is to link CCR data with self-report data from the survey.
>
> 10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

Yes

Identify all data sets and each of the variables to be linked, with a brief description of each variable and justification for each linkage. If there is an extensive list, you may attach that list in the next question and indicate such here.
All study data will use SIDs only. The contact list provided by CSP and the recruitment database will contain names and contact information. A key of study IDs will be kept separate from the study (survey) data. Once we have completed survey collection, we will pull the SIDs from the key and request the clinical variables (from the CCR-approved list) for those men who enrolled in the study.

Attach a copy of the document detailing all data sets and each of the variables to be linked. If you provided this information in the answer to the above question, skip this question.

Approved_Variable List_for SDOHS of AA PrCa survivors in LAC_11.8.24.xlsx	Other Documents

Deleted Attachments: 1 (Most Recent: Approved_Variable List_for SDOHS of AA PrCa survivors in LAC_11.8.24.xlsx on 11/08/2024 8:18 PM ET)

Will a third party be used for data linkage?
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*

Data Security Ltr_Hughes Halbert_Social Determinants of Health Survey 2024_BC.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.

[RESOLVED - there is no database to be kept and no prospective study design] This is confusing with comment above that you intend to have an annotated database and have described the study as now being prospective. If the study is intended to be prospective, what is the estimated timeline for prospection-- this would be related to clarifying when will and what data are to be destroyed?

10/02/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Yes

RETAINED DATA

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

will the patient_id variable be retained?

09/25/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

On the consent form, you ask participants to indicate if they would like to be contacted for future studies. What happens to the data if they indicate yes, won't their PID and contact information be retained?

-- This language was removed in consent form modification on 10/2/2024.

09/26/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

This section might need to be modified further after discussing best approach for minimum data necessary release process. If recruitment identifies the 200 persons, CCR then sends the PHI for these 200 individuals, then patient ID may need to temporarily be retained to assist with linking the PHI with the 200.

This response seems to conflict with response provided in STORING IDENTIFIERS section below. Please clarify.

10/12/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

data will be de-identified

Explain what identifiers will be removed and how.
No registry identification numbers will be retained. Names, addresses, emails and phone numbers will be removed from the study data set, once data collection is complete.
Each participant will be given a Study ID. No registry identification numbers will be retained with the data. Data will be fully de-identified before analysis. We will not ask participants on the consent form if they wish to be contacted for future studies. We will not retain contact information for any of the subjects.
The key linking contact info to study ID will be destroyed after the clinical variables are linked to the SDOH survey.

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.

please clarify if recruitment and eligibility databases are also going into RedCap

10/02/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

The contact list from CSP will be delivered via REDCap. The Recruitment Database will be stored in REDCap, but will be kept separate from the study database.

FAXING

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

No faxes will be used in this study.

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.

No study data will be mailed.

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.

No study data will be stored on laptops of portable storage media (USB drives). All study data will be stored in REDCap.

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.

USC facilities, which store PID in paper or electronic form, have controlled access procedures, and monitored alarm service. Our offices are key card entry only and all online systems have dual-factor authentication logins. All folders/files are password-protected.

SERVER SECURITY

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

All USC servers are kept in secure rooms with controlled access procedures and 24/7 monitoring.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Patient identifiers, such as name/address/phone/email, which will be used for recruitment, will be stored separately from survey study data and clinical variables provided by CSP.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed after the study period.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computers at USC are protected with encryption and passwords. All study data will be kept in REDCap. Any paper forms submitted by participants will be kept in locked drawers in USC offices, at the Department of Population and Public Health Sciences.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

All USC workstations have full disc encryption. PID will be kept behind secure firewall with dual authentication login, in USC's REDCap database.

FIPS 140-2 COMPLIANCE: LAPTOPS

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

All USC laptops have full disc encryption. PID will be kept behind secure firewall with dual authentication login, in USC's REDCap database.

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.

NO PID will be stored on removable media devices.

SECURITY PATCHES

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

All USC workstations and laptops have the necessary security patches installed.

PASSWORD CONTROLS

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

16 character password phrases are in place across all USC systems, and dual authentication is required to access all data and storage systems (e.g., REDCap).

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.

Sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews. These are standard for USC system computers and for USC REDcap.

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

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

All transmissions of 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.

INTERNET ACCESSIBILITY

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

No PID will be accessible to the internet.

DISPOSING OF PID

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

Secure wiping will be used to destroy PID after data collection.

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.

Please include 2 copies of the consent form - 1 for participants to keep and 1 for them to sign and return. Please describe reason for written consent waiver.

[Update 11/6/2024] Please include 2 copies of consent for that indicate 1 is to be kept for participants records and reference back to if LA County Mental Health Services are needed.

10/02/2024 • Jonni Johnson, PhD • *Not* Internal

Update on 10/30--The phone participants should receive the same consent information provided to paper and online participants. The consent form is short enough that the full consent could be read and comprehended over the phone. It is not clear why a waiver of written informed consent would be necessary or appropriate for paper and online participants. These individuals should be provided the opportunity to sign a consent form before participating in the study. The paper consent form can be returned in the mail with the paper questionnaire. Persons participating online can complete and electronically sign the consent form prior to beginning the survey. If the phone participants are fully consented a waiver of written consent would be appropriate for this group.

Please see my earlier note regarding the waiver of written informed consent in the procedures section. The waiver of written informed consent is appropriate when the goals of the study could not be achieved by requiring participants to provide a written signature on a consent form. In this study, there is no obstacle to obtaining written consent for individuals mailing back paper questionnaires or completing online questionnaires. A waiver of written consent may be appropriate for telephone participants, but they will still need to go through an informed consent process. No informed consent process has been described for telephone participants.

10/16/2024 • Laura Lund, MA • *Not* Internal

See instructions and examples on CPHS website.

Consent forms will be mailed with a paper copy of the survey, along with the study invitation letter.
Possible participants will also be called and emailed during the recruitment phase.
The consent form may also be read online in REDCap.
We are requesting a waiver of WRITTEN consent.
A verbal consent text is included in the Phone Script.

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.

[RESOLVED THIS SECTION WAS REMOVED FROM CONSENTS] Can you clarify this section in the consent form:
J. DATA SHARING
Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative. Before your information is used by investigators, all identifiable information will be removed.

[RESOLVED] CPHS approval is only for the study as it is described and not permissible for use in future research studies without additional amendment/application approval. Please clarify the intent of this statement or omit. Additionally, are persons otherwise excluded from the study if they do not consent the involvement in future studies?

The consent form is at a 12th grade reading level - recommend this be simplified to 8th grade, especially if distribution of education attainment for your sample is wide.

[RESOLVED] Please clarify in consent form this statement under voluntary participation: "You should call the investigator in charge of this study if you decide to do this." -- Why are participants being asked to notify the PI?

[RESOLVED] For future studies - and please clarify this intention elsewhere in the project's application sections -- but if this statement stays in the consent form, please add description for the participation of what information is being kept about them for future studies.

[RESOLVED - this in-person option does not appear to be included as modality for collecting the SDOH information of this study] Is there additional parking/payment cost if participants can only come in to have study administered in person?

[RESOLVED] Please clarify language in consent: "However, these are minimal risks, and if you do become distressed you will be offered an opportunity to stop your participation at any time.": Participants should not need to be offered the opportunity to stop participation.

[Updated 11/6/2024] In above procedures, it is indicated that participants can be interviewed via Zoom call, but this option is not listed in email/phone/text scripts. Is this still an optional modality for participants?

09/26/2024 • Jonni Johnson, PhD • *Not* Internal

Other comments on the consent form:
The form states: PROCEDURES AND DURATION
If you agree to be in this study, you will be asked to complete a 30 to 40-minute survey about your health behaviors, and other personal factors such as stress and lifestyle factors that can impact your health. You may complete the survey on paper, by phone, or online with a secure survey link.

This section should provide participants with the kinds of questions they can expect to answer, it should clearly tell participants that there are questions of a highly sensitive nature that some people might find distressing, it should specifically let them know that there are questions related to their experience of their cancer, their finances, mental health, and experiences of crime victimization and interactions with the legal system. This section should also describe that the answers they provide will be linked with their medical information from the cancer registry. If you are planning to create a database for future use using their data (this is unclear in the protocol) this should also be described here.

The form states: RISKS AND DISCOMFORTS
Risks associated with this study may include some mild discomfort with answering survey questions about personal factors that impact your life. There is minimal risk that you will experience distress, but if you are uncomfortable you can decline to answer a question or stop the survey at any time.

This section should clearly state that some sensitive questions, especially those about violent victimization and feeling overwhelmed, may case discomfort for some people. This may be greater than 'mild' discomfort. I believe that the language in this section is misleading. Many of the items are not just 'personal factors' that affect peoples lives, they are actually potentially traumatic. You should also state that being asked about their cancer experience may cause discomfort or anxiety. This section should specifically state what the researcher will do to mitigate those risks. I would recommend including the help resources here in the consent form or as an attachment to the consent form so that people will have them available.

The form states: PAYMENT TO PARTICIPANTS
In return for your time and effort, you will be paid $25.00 (by gift card) for completing the health survey.

--It is misleading to refer to this as a health survey, as it contains more non-health specific items than health items.

--The participant should be clearly told what 'completing the health survey' means. Do they have to answer all the questions? The researcher has previously provided assurances that they do not. It would be best to state something like...when we receive your mailed questionnaire or when you hit 'submit' for the online version of the questionnaire. What constitutes 'completing' for phone interviews? What they have to do to get the $25 should be clearly stated in the consent form.

I recommend that the research participant bill of rights be included in the mailing packet. It is not a requirement with this kind of study but I think it is helpful for participants.

10/16/2024 • Laura Lund, MA • *Not* Internal • Resolved

Scripts and consent forms lack information for completing survey via REDCap link. Please include this

information/include that the link information will be listed on the survey/SDOH.

11/07/2024 • Jonni Johnson, PhD • *Not* Internal

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.

ICF for SDOH survey of AA ProCa survivors_revised 11.8.24.docx	Consent Form
SDOH Phone Email and Text Scripts_11.8.24.docx	Consent Form

Deleted Attachments: 5 (Most Recent: SDOH Phone Email and Text Scripts_11.8.24.docx on 11/12/2024 7:12 PM ET)

HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

> Since this project is federally funded, please change your response in this section from "No" to "Yes" and attach a copy of the project's budget.
>
> 09/10/2024 • Sussan Atifeh • *Not* Internal • Resolved

> There are staff listed on the budget that are not listed as staff working on the project in section above, including a Co-PI. Please clarify and/or add all staff that will be working on the project with access to the data in the sections above.
>
> 09/26/2024 • Jonni Johnson, PhD • *Not* Internal • Resolved

Yes

Attach a copy of your project budget here

Budget for survey study_of AA PrCa SDOH_revised personnel 11.08.24.pdf	Project Budget

Deleted Attachments: 3 (Most Recent: Budget for survey study_of AA PrCa SDOH_revised personnel 11.08.24.pdf on 11/08/2024 6:23 PM ET)

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CHH letterhead_Cover letter to CPHS.docx Cover Letter

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

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

California Department of Public Health: Los Angeles County Cancer Surveillance Program (CSP), California Cancer Registry (CCR)

PI Signature for Coordinator Submission (Initial) - Submitted 09/13/2024 3:10 PM ET by Chanita Hughes Halbert, 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, it will go to the Responsible Official for review and signature, 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 Friday, September 13, 2024 3:10:21 PM ET by Chanita Hughes Halbert, PhD

Responsible Official Signature
- Submitted 09/09/2024 1:03 PM ET by Ricky Bluthenthal, BA, MA, 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 9, 2024 1:03:41 PM ET by Ricky Bluthenthal, BA, MA, 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 09/16/2024 12:17 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

The researchers from USC are conducting a study called the Social Determinants of Health Survey among African American Men with Prostate Cancer (SDOHS) which is federally funded (National Institute of Minority Health and Health Disparities grant #U54MD010706.).
This study focuses on collecting and analyzing data about the health and social factors that affect African American men who have survived prostate cancer. The goal is to understand how factors like neighborhood, social isolation, financial strain, and stress contribute to prostate cancer outcomes. They will gather both clinical data and information directly from the patients through surveys.
The study is happening in Los Angeles County and aims to enroll up to 200 African American men who were treated for prostate cancer between 2017 and 2023.

Data Sources:
•Los Angeles Cancer Surveillance Program (CSP) and California Cancer Registry (CCR)—A LOS from CCR is attached.
•Surveys (conducted via REDCap, phone, mail) will collect social, behavioral, and demographic data from participants.

Data Linkages:
They will link clinical data from the CSP and CCR with the social and demographic information collected through the patient surveys. These linkages will help them understand how social determinants impact prostate cancer outcomes.

Important Points About the Project:

Purpose: The project aims to examine how social and health factors (like neighborhood conditions, stress, and financial strain) influence the health outcomes of African American men who have survived prostate cancer.
Procedures:
• Identification and Recruitment: Eligible patients will be identified by the CSP and contacted by the study team. Participants will receive an introductory letter, followed by phone calls, texts, or emails to complete a survey about their health and social environment.
• Survey Completion: Participants will complete a baseline questionnaire about their social and behavioral conditions, either online, via phone, or by mail.
• Clinical Data: will be collected from the CSP and CCR.
• Requested State Data: • Data from the California Cancer Registry (CCR) and Los Angeles Cancer Surveillance Program (CSP) will be used to gather clinical information about the participants, including diagnosis, treatment, PSA levels, cancer stage, and other clinical variables.

• Human Subjects Contacts: Researchers will contact up to 200 African American men via phone, email, mail, and text messages to recruit them and gather survey data.

Choose the CPHS Chair
Darci Delgado, PsyD

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

Assign to Cycle

October

Assign to cycle year
2024

Load into IRBManager (Initial Submission)
- Submitted 11/12/2024 7:13 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 09/16/2024 12:20 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2024-149

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 researchers from USC are conducting a study called the Social Determinants of Health Survey among African American Men with Prostate Cancer (SDOHS) which is federally funded (National Institute of Minority Health and Health Disparities grant #U54MD010706.).
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• Human Subjects Contacts: Researchers will contact up to 200 African American men via phone, email, mail, and text messages to recruit them and gather survey data.

Assign SME to study

Jonni Johnson, PhD

Enter the meeting date for this project

10/04/2024

SME Review

SME review

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

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

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

Yes

Enter any additional comments that you have for the researcher (in addition to your notes) here.
Please see and address additional comments in IRB manager.

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