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 09/09/2024 12:22 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

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.

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

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

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

Minimal Risk
HIPAA waiver
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

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.*

New project requesting only previously existing PHI/PIDs and not involving state research staff, funding or state mental hospital patients from departments within the CHHSA (Common Rule review)

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

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

07/05/2024

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.

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 among African American Men with Prostate Cancer (SDOHS). The SDOHS aims to prospectively collect, track, 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 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 future cancer research by the study team. The end product will be a research report and/or article.

MAJOR RESEARCH QUESTION

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

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

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. For each patient who consents to be included in the database, an ID will be created that will allow us to link and retrieve all data points for patients when conducting analyses. Once this is complete, we will begin collecting data at the initial point they join the study. This would include baseline health and SDOH surveys. 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, treatment completed, PSA, stage of disease at diagnosis, comorbidities). Through the process of collecting patient-specific data matched with clinical characteristics, we will create a high-quality database that can support future studies.

1 Patient Identification

Eligible patients will be identified by CSP.

2 Recruitment

Registry staff at 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, baseline questionnaire, and a postage paid return envelope, and instructions for completing the questionnaire via other modes (i.e., 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 send a second set of study materials to those who do not respond after 4 weeks of initial contact. The average number of calls per patient will range from 3-5, however, additional follow-up phone calls may be conducted depending on the type of contact performed, 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.

The informed consent form will be offered in the mailing packet and at the beginning of the REDCap survey.

3 Survey

Following informed consent, participants may complete the baseline SDOH questionnaire online through REDCap. Participants can complete the electronic questionnaire at home on their personal computer, independently on a tablet computer available at the study office, or the research coordinator can read the questions aloud (in a private area at the clinic or by phone or Zoom call) and enter their responses on the tablet if they prefer. Participants who opt to complete the questionnaire online in REDCap may receive reminder calls, email or text messages to complete the

questionnaire.
4 Clinical Data Abstraction
Clinical variables will be abstracted from the CSP case report and recorded on the electronic Case Report Form in the study database. If the information on the Case Report Form cannot be located in the CSP case report, it may be obtained from the participant via clinical interview conducted by the study coordinator.
5 Data Collection
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, at least three attempts will be made to contact patients through different modalities (e.g., telephone, texting, email, mail).

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.

USC Health Equity Project 1_SDOH Survey_FINAL.doc Instruments

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

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	Cancer Registry

Study Population

POPULATION DESCRIPTION

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

Adult African American men diagnosed with prostate cancer, in LA County, who were treated with radical prostatectomy from 2017 through 2023.

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.

Up to 200 men will be enrolled. Subjects will participate in a survey study.

DATABASE DETAILS

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

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

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

LA County Cancer Surveillance Program 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, baseline questionnaire, and a postage paid return envelope, and instructions for completing the questionnaire via other modes (i.e., 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 send a second set of study materials to those who do not respond after 4 weeks of initial contact. The average number of calls per patient will range from 3-5, however, additional follow-up phone calls may be conducted depending on the type of contact performed, 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. LACSP will provide contact information: name, address, email, phone number.
Clinical characteristics will be requested for those men who enroll in the study. Clinical variables are attached here.

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.

Variable List_for SDOHS of AA PrCa survivors in LAC.xlsx List of Variables

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.)?

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, baseline questionnaire, and a postage paid return envelope, and instructions for completing the questionnaire via other modes (i.e., 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 send a second set of study materials to those who do not respond after 4 weeks of initial contact. The average number of calls per patient will range from 3-5, however, additional follow-up phone calls may be conducted depending on the type of contact performed, 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.
The informed consent form will be offered in the mailing packet and at the beginning of the REDCap survey.

Attach copies of all recruitment materials.

Recruitment Letter for SDOH survey 6.18.24.docx Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

No

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.

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 30-40 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.

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.

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.

No services will be provided.

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.

The survey study is minimal risk. There are no less risky methods available.

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 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)
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.

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-sued or shared with any unauthorized persons.

CONFIDENTIALITY OF PUBLISHED DATA

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

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

DATA REQUEST JUSTIFICATION

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

We 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 CSP Co-I). 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.

The PI will provide data management, processing, and analytic services for this project.
1. The original data collection forms will be kept in secure file cabinets.
2. All electronic patient 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 will use patient ID numbers (PIDs) only and never include names or any other personal information.
5. All data sets will use PIDs only.
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.

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

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

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.

Yes

RETAINED DATA

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

data will be de-identified

Explain what identifiers will be removed and how.
Names, addresses, emails and phone numbers will be removed from the data set, once data collection is complete.

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.

Paper data forms will be cross-cut shredded, after data collection is completed, and all data variables are entered into REDCap.

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.

Mailings of PID are sealed and secured from inappropriate viewing. Completed surveys may be mailed back to our study office in a sealed and secure pre-paid envelope. No other 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.

See instructions and examples on CPHS website.

Consent forms will be mailed with a paper copy of the survey, two weeks after the study invitation letter.
Possible participants will also be called and emailed during the recruitment phase.
The consent form may also be completed online in REDCap.

CONSENT FORMS

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

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

ICF for SDOH survey of AA ProCa survivors 2024.docx Consent Form

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

No

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: Cancer Registry

PI Signature for Coordinator Submission (Initial) - Submitted 09/09/2024 12:51 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 Monday, September 9, 2024 12:51:47 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

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