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 11/13/2024 9:29 PM ET by Laura Allen, BA

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

December 2024 cycle.

----------HSC New Project----------

A LOS from CCR is attached which is not in the recommended format.

11/05/2024 • Sussan Atifeh • Internal

Researchers from UCSF have submitted this application to request CPHS approval (as the IRB of record for an entire multi-site study led by UCSF and involving NYU Langone Health) for a project, funded by the CDC, seeks CPHS.
• The project is aimed to evaluate patient perspectives on prostate cancer pathology terms through focus groups, interviews, and surveys, with data managed and housed at UCSF.
• A DSL from UCSF is attached.
• Researchers have requested PII from CCR to identify eligible participants diagnosed with low-grade prostate cancer (GG1) in California.
• A Letter of Support (LOS) from CCR is attached but it does not follow the requested format specified on the CPHS website.
•This project wants to rely on CPHS as the overseeing IRB of record for this multi-site project and (after the approval of the study by CPHS) they plan to submit amendment by attaching the fully signed reliance agreement form(s) (signed by their perspective IRBs and CPHS Chair) to document this agreement in the project application.

• Human Subjects: The study involves direct contacts with human subjects via recruitment from the CCR, focus groups, and interviews, with a primary focus on Black and Hispanic men, representing California's racial and socioeconomic diversity.

1. Qualitative Focus Groups: Conducted by NYU Langone, with diverse patients discussing pathology report terminology,

particularly around “cancer” vs. “neoplasm/lesion.”
2. One-on-One Interviews: Gather in-depth input on patient preferences for terminology and care options, which will inform a Discrete Choice Experiment (DCE).
3. Quantitative Survey: A DCE survey with 525 participants to explore how terminology and diagnosis labels impact patients’ perceptions of treatment options.

11/05/2024 • 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,

11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

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.

Matthew Cooperberg, MD

Email: matthew.cooperberg@ucsf.edu **Business:** (415) 885-3660

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

University of California, San Francisco

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

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.

MC - 092024 CV.pdf PI Curriculum Vitae

Deleted Attachments: 2 (Most Recent: CV_Scarlett Gomez_Nov2021.docx on 09/11/2024 8:07 PM ET)

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.

Scarlett L Gomez, PhD

Email: scarlett.gomez@ucsf.edu **Business:** (510) 608-5041

Stacy Loeb, MD

Email: stacy.loeb@nyulangone.org **Business:** (718) 261-9100

Attach a copy of each Co-PI's Curriculum Vitae.

CV_Scarlett Gomez_Nov2021.docx	Co-PI Curriculum Vitae
Loeb Biosketch.pdf	Co-PI Curriculum Vitae

Deleted Attachments: 1 (Most Recent: Scarlett Lin Gomez updated CV Oct 2021.docx on 09/11/2024 7:26 PM ET)

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.

Laura Allen, BA

Email: laura.allen@ucsf.edu **Business:** (510) 608-5061

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.*

Iona Cheng, PhD

Email: iona.cheng@ucsf.edu **Business:** (650) 279-8254

OTHER RESEARCH STAFF

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

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

11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

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.

Nataliya Byrne, BA
Email: nataliya.byrne@nyulangone.org **Business:** (646) 501-2681

Zinnia Loya, BA
Email: zinnia.loya@ucsf.edu **Business:** (925) 323-8948

Tatiana Sanchez-Nolasco, MPH
Email: tatiana.sancheznolasco@nyulangone.org **Business:** (646) 501-2550

Mariana Rangel-Camacho, BSc
Email: mariana.rangelcamacho@nyulangone.org **Business:** (646) 501-2552

Leslie Wilson, Ph.D.
Email: wilsonl@pharmacy.ucsf.edu **Business:** (415) 990-1012

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

False

Project Information

SUBMITTER

Application completed by:

Laura Allen, BA

Email: laura.allen@ucsf.edu **Business:** (510) 608-5061

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).

Patient Perspectives on Relabeling and Pathology Reporting for Grade Group 1 Prostate Cancer

PROJECT SITE

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

University of California, San Francisco

STUDY PROCEDURES

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

If you are using any state data for conducting this project, please select "Data Registry" in this section and attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in the "DATABASE DETAILS" section.
In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables.

Also you need to attach a support letter (following the format specified on the CPHS website) from the data providing department in the Support Letter section of this application (please see the note in the Support Letter section of this application).

Thanks,

11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

Data Registry
Focus Groups
Interviews
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

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

> CPHS is mandated to conduct an Information Practices Act (IPA) review for your project (since you have requested state personally identifiable information to conduct this research) to ensure compliance with privacy and security requirements for state-held data. Please select "Information Practices Act" as well as "Common rule/Human subjects."
>
> 11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

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

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

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

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

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

PROJECT TYPE DETAILS

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

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

Minimal Risk
Non-English translation required
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.
Centers for Disease Control

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.

This project has human subjects' contacts components and is not eligible for an Expedited review. Please select "Not Applicable."

11/05/2024 • 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 12/6/24 or a date following this date within a few weeks.

11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

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

12/06/2024

ANTICIPATED PROJECT END DATE

09/29/2027

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.

There is considerable debate about removing the label of "cancer" from low-grade prostate cancer due to its indolent natural history. A related challenge is the optimal patient-centered presentation of pathology reports in the era of immediate electronic access to clinical results. A critical research gap is the perspective of diverse patient populations on prostate cancer nomenclature and pathology reporting. We will address this gap through 3 key approaches: (1) qualitative studies of patient perspectives on prostate cancer nomenclature and preferences for a patient-centered pathology report. (2) discrete choice experiments to determine the impacts of changes in nomenclature for low-grade prostate cancer. (3) a randomized study to test the usefulness of alternative wording in pathology reports and of patient-centered pathology. We will explicitly sample Black, Hispanic, and other men reflecting the broad geographic and socioeconomic diversity of California. All stages of the study will be conducted in English and Spanish. The expected outcomes of this study will advance the field by studying the optimal prostate cancer nomenclature and pathology reporting in diverse patient populations.

All study activities will take place remotely (via Zoom) and online surveys with all potential participant data stored at UCSF. As such, no Data Security Letter is needed for NYU (as confirmed by CPHS guidance). A UCSF Data Security Letter is attached.

Please note that this protocol has an iterative study design, with a focus group, qualitative phase informing subsequent study instrument development. As such, this submission includes only study documents for the initial, focus group phase.

Also, this project intends to rely on CPHS as the overseeing IRB of record for this multi-site project. We were provided guidance from the Deputy Director, Insights Lab, Center for Data Insights and Innovation (CDII),
CA Health & Human Services Agency (CalHHS) to make a note regarding this for this initial submission, but to select "relying on CPHS" once this application and the consent forms are approved--then we can submit, with CPHS approval, to our respective IRBs to sign the CPHS reliance agreement, afterwhich we will select the reliance on CPHS option and attach signed reliance agreements as an amendment.

MAJOR RESEARCH QUESTION

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

The major research question in this project is to explore the perspectives of diverse patients with prostate cancer on pathology reporting and grading nomenclature.

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

Qualitative Focus Groups: The research team at NYU will perform virtual focus groups through a secure UCSF Zoom platform with patients diagnosed with GG1 prostate cancer, recruited from CCR caselistings and oversampling of Hispanic and non-Hispanic Black patients. Participants will be screened by the bilingual research coordinator to confirm eligibility. Separate focus groups will be conducted for English-preferring and Spanish-preferring patients. We will perform approximately 6 focus groups with 4-6 participants per group, and enroll additional groups until theoretical saturation is reached. Focus group facilitators and interviewers will be bilingual. Electronic consent will be obtained through the online UCSF REDCap platform prior to the focus group, followed by a brief online intake questionnaire to assess sociodemographics and health literacy. The qualitative guide is attached below. The focus group will begin with discussion about Gleason grading, including preferred terminology and implications for patient anxiety. We will also discuss the impact of relabeling for clinical decision-making and whether patients on Active Surveillance (AS) protocols would continue or modify disease monitoring of AS if their tumor were relabeled as non-cancer. Next, we will discuss the participants' perspectives on deidentified sample pathology reports. We will ask their perspectives on various terms (e.g., carcinoma vs. neoplasm vs. lesion). Sample hypothetical pathology reports (both standard and patient-oriented) will be projected to stimulate discussion, and participants will be asked to provide suggestions for more comprehensive and patient-centered messaging. Finally, we will ask them to discuss attributes that are important to their decision-making (focusing on risks, benefits, and management). We ask participants to spontaneously list attributes and then show the participants a preliminary list of attributes from the previous literature to get their input as to which attributes are most or least important. The focus group is expected to take approximately 90 minutes. Descriptive statistics will be used to summarize baseline characteristics of the focus group participants. De-identified focus group transcripts will be imported into NVivo qualitative software for further organization and analysis. We will develop a codebook using inductive and deductive approaches. Transcripts will be independently analyzed by two members of the study team experienced in qualitative research. The team will regroup for consensus on the codebook, and coding of the transcripts. The thematic approach uses a constant comparative method, which will continue until thematic saturation is reached. The final number of focus groups will depend on the achievement of saturation. Disagreements around codes, themes and subthemes will be resolved by team discussion. All study data and registry data will reside at UCSF, behind UCSF firewalls. All NYU staff will access study and registry data only through UCSF REDCap databases and shared, secure drives behind the UCSF firewall.

Note that the project phases are intended to be iterative, with prior phases informing subsequent. The recruitment and other study documents for the below phases of the study will be submitted as amendments. None of the below study activities will take place until these documents and protocols are approved.

Qualitative One-on-One semi-structured interviews: The objective of the one-on-one qualitative interviews is to identify 7 to 9 key attributes that are important to patients diagnosed with GG1 prostate cancer concerning the nomenclature used in pathology reports and the preferred follow-up care scenarios. We aim to develop and utilize two discrete choice experiment (DCE) instruments to measure patient preferences for these attributes related to GG1 diagnosis labeling, pathology reporting, and follow-up care strategies. DCE is a method used to understand preferences by presenting individuals with choices between different sets of alternatives. Each alternative is characterized by a set of attributes with varying levels. Participants are asked to choose their preferred option from these sets, and their choices reveal the relative importance they place on the different attributes. This method helps in estimating the value individuals place on specific attributes and predicting their decision-making behavior in real-world scenarios

The study will include qualitative methods, where we will conduct 15 semi-structured interviews with patients who have a GG1 diagnosis. These interviews will help us determine the most relevant attributes by capturing a range of patient perspectives. We plan to involve a diverse group of participants, aiming for a balanced representation including approximately 5 non-Hispanic Black, 5 Hispanic patients, and 5 other patients, ensuring broad demographic and socioeconomic diversity. The interviews will be conducted in both English and Spanish to accommodate participants' language preferences.

Additionally, we will pilot test the DCE instruments with 30 patients (10 Black, 10 Hispanic, and 10 other) and refine the tool based on feedback. This process will also involve input from 10 prostate cancer experts to ensure clinical relevance and accuracy. Through this comprehensive approach combining expert and patient perspectives, the study seeks to refine how pathology reports and follow-up recommendations are communicated to patients with GG1 prostate cancer, enhancing patient understanding and satisfaction with their care options.

Quantitative online survey: In the quantitative phase of our study, we aim to explore patient preferences using a Discrete Choice Experiment (DCE) in two main areas: treatment and diagnostic labeling. Firstly, we'll assess how patients weigh the risks and benefits of follow-up approaches, comparing sample, de-identified pathology reports labeled with a cancer diagnosis to those without. Secondly, we'll evaluate patient preferences for the wording used in the pathology reports—whether they prefer traditional "cancer" terminology or a softer approach.

We plan to recruit 525 participants from the California cancer registry,

ensuring diversity with equal representation from Black, Hispanic, and other backgrounds. The study will involve completing online surveys that will be administered using Sawtooth Software, a web-based HIPAA compliant DCE delivery platform. The survey will also include questions about demographics, anxiety, and treatment regret. We'll use Sawtooth to design and administer the surveys, aiming to gather detailed insights into patient preferences that could influence future diagnostic and treatment protocols for GG1 prostate cancer.

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.

Aim 1 FG guide.docx	Questionnaires
CDC SIP Qualitative Intake Questionnaire (1).docx	Questionnaires

Deleted Attachments: 1 (Most Recent: CDC_GG1_VarList.xlsx on 11/07/2024 3:52 PM ET)

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).
audio-recordings of the focus group and one-on-one meetings will be saved on secure study drives. The recordings will be transferred securely to the HIPAA-compliant Transcription service we will contract with and de-identified transcripts will be securely transferred back to the study. Audio recordings will be destroyed once analyses have completed, to ensure transcripts accurately reflect participant input.

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

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

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

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

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

Study Population

POPULATION DESCRIPTION

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

Participants will be:
- Any Race/ethnicity with oversampling of Hispanic and non-Hispanic Black patients
- 18 years of age or older males
- live in the United States
- diagnosed with low grade (GG1) prostate cancer within 3 years of contact
- speaks English or Spanish
- access to internet with audio/visual capabilities

Target sample size for focus groups: N=36
Target sample size for qual one-on-one: N=15 + 10-15 individuals who participated in the focus groups
Target sample size for pilot study: N=30 patients + 10 prostate cancer experts
Target sample for quantitative study: N=525

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.

Participants will not be involved in other studies.

Please see attached variable list for list of variables requested and justification.

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

Reviewed_Cooperberg_GG1_ProstateCancer_VarList_UPDATED.xlsx	List of Variables

Deleted Attachments: 1 (Most Recent: Reviewed_Cooperberg_GG1_ProstateCancer_VarList_UPDATED.xlsx on 11/13/2024 9:28 PM ET)

RATIONALE

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

The rationale for studying the requested group is that there is currently controversy surrounding the optimal terminology for prostate cancer grading, and optimal method of patient-centered pathology reports. In particular there are limited data on perspectives of diverse patients with prostate cancer (e.g., Hispanic and non-Hispanic Black).

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.

Eligible participants will be identified through the statewide CCR: diagnosed within the prior 3 years with Gleason Grade 1 (GG1) prostate cancer, resident of California, age 18 or over, able to speak English or Spanish.

We will send recruitment letters, along with study flyer and CCR flyer to cases who meet the above eligibility criteria. Study team with follow up with a telephone screener to answer questions and recruit interested participants with an eligibility screener for the focus group phase of the study. Interested and eligible participants will receive mail/email/telephone correspondence with consent form and instructions to complete an online questionnaire on race/ethnicity and other demographic items and logistics for the focus group. The consent document will also be read by study facilitator before the focus group meeting. Reminder emails/phone calls will be made the day before the scheduled focus group meeting. Participants may complete the online questionnaire online or via telephone interview.

The recruitment of cases who meet the above eligibility criteria will be based on our well-established prior protocols. Eligible cases identified from the CCR will be mailed a letter introducing the study, a study brochure, and a response form to indicate their availability or refusal to participate. The materials will be printed in Spanish and English. All study instruments will be translated by certified translators. After one week, one of our trained interviewers will contact cases by telephone. Multiple calls will be attempted at various days of the week and times of the day. If the case is eligible and agrees to participate, study staff will proceed to scheduling of focus group and sent a link to the online consent and questionnaire. For patients whose letters are returned due to invalid address, we will request CCR-approved subject searching methods to find an updated address. The focus group interviews will be approximately 1.5 hours, online or telephone questionnaire will take approximately 5-15 minutes to complete. The qualitative interviews will be audio-recorded and follow an open-ended, guided conversational format based on a topics guide. The online questionnaire will be quantitative.

Attach copies of all recruitment materials.

Eligibility Screener_GG1.docx	Recruitment Materials
Email Template_screened.docx	Recruitment Materials

Flyer_10312024.docx	Recruitment Materials
Focus Group Interview Appointment ConfirmationGG1.docx	Recruitment Materials
NonParticipantScriptGG1.docx	Recruitment Materials
PtInvitationLetter_GG1.docx	Recruitment Materials
Response_form_GG1.docx	Recruitment Materials
Telephone Contact Script_GG1.docx	Recruitment Materials

Deleted Attachments: 2 (Most Recent: CDC SIP Qualitative IRB blurb.docx on 10/31/2024 7:39 PM ET)

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
Potential participants to the focus group will be screened for eligibility by study team members.

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.
Focus group participants will receive a $40 electronic gift card as compensation for their time. Participants in the qualitative one-on-one and baseline surveys will receive a TBD gift card as compensation for their time completing the online survey.

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.

Participants in phase I will attend a 90-minute, one-time focus group, preceded by a short 5-15 minute quantitative online or telephone questionnaire. Total approximate time commitment for participants of the focus group is 1.75 hours.

As study surveys and qual guides for the one-on-one interviews and epidemiologic surveys will depend on focus group analysis, estimated time commitment to complete these phases will be updated as an amendment.

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.

Risk level for this study is minimal. Male prostate cancer patients will be involved in this proposed study. Their involvement is limited to providing information via qualitative interviews and brief online questionnaire about opinions about nomenclature on path reports, diagnosis and treatment experiences, and sociodemographic information. For the qualitative data, we will contract with a HIPAA-compliant transcription service to transcribe audio recordings and transcripts will be deidentified and stored on the secure server at UCSF. One potential risk of the study includes a breach in confidentiality; however, multiple safeguards are in place to ensure information security, including that all transcripts will be deidentified. All data safety and privacy measures will be taken; however, an accidental breach of data may occur, though the chances are extremely low. Some participants may feel uncomfortable or anxious about responding to questions about their diagnosis. However, we will take various measures to attempt to reduce these feelings. Research staff and interviewers will be trained to be sensitive to participants' emotional reactions, if they occur during qualitative interviews, and they will remind participants that they can refuse to answer any questions they do not wish to answer and participants can skip any questions they do not wish to answer on the online surveys. Subjects will be informed that participation is voluntary and that they may participate in all or part of the study. We will minimize the risk of loss of confidentiality by maintaining identifying information in password-protected databases and behind UCSF firewalls, training staff to follow confidentiality guidelines, keeping documents in locked cabinets, destroying audio recordings at the end of the study, and presenting epidemiologic results as statistical summaries.

Additional steps to maintain confidentiality include:
All study staff will be trained to follow all UCSF confidentiality procedures and will complete confidentiality training as well as the CITI human subjects protection training. We will use a UCSF-maintained RedCap secure, password-protected Tracking Database. This system will be accessible to designated study staff only. Each potential participant will be assigned a unique study ID by study staff. No preliminary or final results will be released or published with identifying information and all
data will be presented as statistical summaries such that individuals cannot be identified. De-identified study data will be made available to other investigators under data sharing agreements that ensure that the data will be used only for research purposes, that any individual participant's data will not be disseminated, that the data will not be used to identify an individual participant, that data will be protected under appropriate security measures including encryption and password protection, and that the data will be destroyed or returned to us upon completion of relevant analyses.

Data will not be accessible to the Internet. RedCap tracking datasets will be stored on the UCSF networks only. The secure web-based RedCap surveys, which identify participants by study ID number, will be made accessible to study staff with authenticated login credentials only. Laptop computers will never be left unattended in cars or other unsecured locations. Laptops will provide access to personally identifying data only via VPN from a secure remote site.

AUDIO/VIDEO RECORDING RISKS

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

Audio-recordings of the focus group meetings will not increase the minimal risk described above. Recordings will be saved on secure study drives. The recordings will be transferred securely to the HIPAA-compliant Transcription service we will contract with and transcripts will be securely transferred back to the study. Audio recordings will be destroyed once analyses have completed, to ensure transcripts accurately reflect participant input.

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.

As this research presents minimal risk to subjects, no medical 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.

This research presents minimal risks to subjects.

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.

While there is no direct benefit for participants, this study has the potential to inform changes in the way that pathology reports and prostate cancer grading are presented for patients. This may help to improve the quality of care delivery and reduce anxiety for patients in the future.

JUSTIFICATION OF RISKS

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

The minimal risks of participating in the study are justified based on the importance of the scientific question and gaining perspectives from diverse patients 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)
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 study staff will be trained to follow all UCSF confidentiality procedures and will complete confidentiality training as well as the CITI human subjects protection training.

STAFF VETTING PROCEDURES

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

All study staff have been thoroughly vetted.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

Would you please provide a new Support Letter following the format specified on the CPHS website? please do not delete the already attached letter in this section.

Please note, a Support Letter should certify a "preliminary or initial review" has been done by the data-source department and the release of data will be in compliance with all applicable state and federal statutes.
You can refer to the CPHS webpage for information regarding Letter of Supports (LOS) and other resources at: https://www.cdii.ca.gov/committees-and-advisory-groups/committee-for-the-protection-of-human-subjects-cphs/ under "FORMS AND BULLETINS."

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

11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

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.

CCR_Grant_LOS_Cooperberg, M.docx (1).pdf	Department Letter of Support

CPHS_LOS_Cooperberg, M.docx.pdf	Department Letter of Support

Deleted Attachments: 1 (Most Recent: New Project Approval Letter.pdf on 09/11/2024 8:13 PM ET)

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

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

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

• Identifiable data will not be reused or provided to any persons outside of the research team.
• Data will not be accessible through any publicly available Internet website or link.
• De-identified study data will be made available to other investigators under data sharing agreements that ensure that the data will be used only for research purposes, that any individual participant's data will not be disseminated, that the data will not be used to identify an individual participant, that data will be protected under appropriate security measures including encryption and password protection, and that the data will be destroyed or returned to us upon completion of relevant analyses. All investigators requesting data will be expected to complete a Data Use Certificate and complete the required training on IRB regulations, human subjects research, and HIPAA.

CONFIDENTIALITY OF PUBLISHED DATA

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

No preliminary or final results will be released or published with identifying information and all epidemiologic data will be presented as statistical summaries.

DATA REQUEST JUSTIFICATION

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

We have requested the minimum necessary variables and years of data to recruit (via mail, email and telephone) a sufficient number of patients to meet recruitment goals.

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.

Access to data will be available only to eligible study staff who will sign and adhere to procedures outlined in CCR Appendix 2 as described above. Computerized databases containing case identifying information will be maintained on secure UCSF networks, and will be accessible only to eligible study staff via password-secured
computers. Only eligible study staff will be allowed to access the study databases for purposes of implementing or evaluating the research.

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.

No preliminary or final results will be released or published with identifying information and all data will be
presented as statistical summaries such that individuals cannot be identified.

LINKAGES

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

No

DESTRUCTION OF PID VERIFICATION

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

Yes

DATA SECURITY LETTER

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

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

CPHS Letter - Matthew Cooperberg - Patient Perspectives on Relabeling and Pathology Reporting.pdf	Data Security Letter

Deleted Attachments: 1 (Most Recent: UCSFData Security Letter 091119.pdf on 09/11/2024 8:25 PM ET)

Physical Safeguards

DATA PROTECTION

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

Yes

DATA DESTRUCTION

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

Yes

RETAINED DATA

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

data will contain personal identifiers

DESTRUCTION METHODS

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

All PID in paper forms will be disposed of through confidential meansthr ough cross cut shredding.

FAXING

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

It is not anticipated that we will need to fax PID for this study, but, shouldthe need arise, faxes with PID will have a coversheet marked confidential. Fax machines are located in a secured area.

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.

Other than mailing recruitment letters addressed to potential participants, it is not anticipated that we will need to mail PID for this study, but should the need arise, mailed PID will be transported in a protected manner (closed work bag, envelope, etc). Materials with identifying information sent to and from the office shall always be sent by a secure carrier and enclosed within an outside envelope in a separate sealed envelope with a CONFIDENTIAL stamp. There will be no mailings of 500 or more individually identifiable records of PID in a single package.

ELECTRONIC STORAGE

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

PID in paper or electronic form and laptop computers will never be left unattended in cars or other unsecured locations. Any study data stored on laptop computers will be encrypted.

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.

Yes, facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.
For proper functioning of security technology and equipment, the followings are implemented:
• Installation and maintenance of intrusion and alarm systems
• Access control systems
• Closed circuit television systems (CCTV)
• Emergency call buttons across the campuses
• Installation, service and repair of building access security
• Card reader access control systems
Exterior access to secured campus buildings is by proximity card (which also serves as an employee ID badge). These are issued by the UCSF Campus Police Department "We ID" program. The UCSF Police Department manages the database that controls access through identity proximity cards. Access is granted either by a department representative or the UCSF Police Department.

SERVER SECURITY

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

Yes, all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

We will use study ID numbers to detach PID from the data. Specifically, identifying information for recruitment (i.e. names, contact address, and phone numbers) will be located in separate secured databases, behind UCSF firewalls and detached from questionnaire data and focus group transcripts. For the RedCap survey, registration information (names, email addresses and/or cell phone numbers) will be stored in a separate data module from the study data. In the tracking system study ID numbers and identifying information will be password-protected, with only the Principal Investigator and authorized staff having access to this information for purposes of communication and mailing materials. The study ID number will be the only identifier for the analysis data. Sawtooth platform will store only a unique identifier.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed when the research has concluded.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

Password-protected computerized tracking databases containing caseidentifying information will be
accessible only to eligible study staff via UCSF-maintained REDCap database that resides behind UCSF firewalls.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

All workstations running DDPE and File Vault are FIPS 140-2 certified

FIPS 140-2 COMPLIANCE: LAPTOPS

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

PID will not be stored on any laptops.

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.

UCSF Information Technology manages and maintains all security patches for applications and systems used in the UCSF network. All workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

PASSWORD CONTROLS

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

This Unified UCSF Enterprise Password Standard was approved by the UCSF CIO on October 1, 2010, and is applicable to all Electronic Information Resources within UCSF, including the Medical Center.
Failed logons allowed before lockout: 5 failed attempts
Lockout duration: 15 minutes
Minimum password length:7
Maximum consecutive character repeats:2
Required characters: At least one in 3 of 4 character sets: Upper/lower case, numbers, symbols
Prohibited patterns: Easily guessed patterns: dates, phone numbers, proper names, minor variations on former password
This standard should be considered a minimum.

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.

Yes to all of the above.

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.

We do not anticipate transmission of electronic PID outside the secure internal network, however, should the need arise, for emails, all data is encrypted using 7 zip encryption which has been validated to FIPS-140-2. There will be no PID transmitted via website.

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.

Electronic PID will be destroyed by secure wiping.

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.

Informed consent procedures for Focus Group: We request waiver of written consent for this minimum-risk questionaire and virtual (Zoom) meetings phase. Participants who are screened eligible, will be sent a link to complete the consent and questionnaire. The consent form will be the first document the participant sees when they click the link. Once they read the consent form and click to proceed, they have consented to participate in the survey portion of the study. For participants who prefer telephone surveys, interviewers will read the consent document and answer any questions prior to conducting the telephone questionnaire. For the virtual focus group meetings, we will obtain verbal consent from participants at the beginning of each session. Participants will be mailed or emailed a copy of the consent form prior to the virtual group meeting. They will be asked to read the form ahead of time. At the initiation of the Virtual group meeting, facilitators will go over all sections of the consent form with participants, ensuring everyone understands all sections and that participants will use first names only during the group session. Researchers will also ask participants not to tell anyone outside the group what any particular person said in the group and will inform them also, however, that the researchers cannot guarantee that everyone will keep the discussions private. Facilitator will ask each participant if he has questions about participation prior to proceeding. He/she will ask each participant individually if he consents to participate in the virtual group meeting, as described in the form. Anyone who does not consent will be thanked for their time and asked to leave the focus group Zoom meeting.

Translated copies of the focus group consent and updated translation certificate will be submitted once there is an approved version in English.

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.

CDC SIP_ICF_FG.docx Consent Form

TRANSLATED DOCUMENTS

Provide copies of the non-English version of consent/assent forms and/or scripts to be used in this research.

CDC SIP_ICF_FG_SpanishTBD.docx Consent Form

TRANSLATOR

Provide a copy of the curriculum vitae of the translators(s) and/or proof of certification of the translation firm.

CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. For studies using documents translated into Spanish, the translation should use formal language.

TranslationCertificate-NWTranslations.pdf Translator Curriculum Vitae

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?

Yes

Attach a copy of your project budget here

Draft Budgt Justification GG1-Prostate-final 02 12 24.docx	Project Budget
NYU Budget Justification (1).docx	Project Budget

COVER LETTER

Attach a copy of your project cover letter.

This project has human subjects' contacts components and is not eligible for an Expedited review. Please revise the attached Cover Letter.

A cover letter describes your study briefly in one page (a few paragraphs) and gives a quick understanding of your project. It should be on your institution's letterhead and should be signed by you (as the PI of the project). Please emphasize on the major points regarding the purpose and goal of the study and major steps necessary to complete your project (for example which departments you requested data from, which documents you prepared and attached to the application, etc.)

11/05/2024 • Sussan Atifeh • *Not* Internal • Resolved

Cover letter must have the requesting institution's letterhead.

CoverLetterGG1_v1.1.pdf Cover Letter

Deleted Attachments: 1 (Most Recent: CoverLetterGG1_v1.1.pdf on 11/07/2024 3:26 PM ET)

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

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

California Department of Public Health: California Cancer Registry

PI Signature for Coordinator Submission (Initial) - Submitted 11/14/2024 12:30 AM ET by Matthew Cooperberg, MD

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 Thursday, November 14, 2024 12:30:04 AM ET by Matthew Cooperberg, MD

Responsible Official Signature
- Submitted 11/03/2024 1:43 AM ET by Iona Cheng, 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 Sunday, November 3, 2024 1:43:37 AM ET by Iona Cheng, PhD

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

Notify IRB for Pre-Screening
- Submitted 11/14/2024 7:34 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

Researchers from UCSF have submitted this application to request CPHS approval (as the IRB of record for an entire multi-site study led by UCSF and involving NYU Langone Health) for a project, funded by the CDC, seeks CPHS.
• The project is aimed to evaluate patient perspectives on prostate cancer pathology terms through focus groups, interviews, and surveys, with data managed and housed at UCSF.
• A DSL from UCSF is attached.
• Researchers have requested PII from CCR to identify eligible participants diagnosed with low-grade prostate cancer (GG1) in California.
• A Letter of Support (LOS) from CCR is attached but it does not follow the requested format specified on the CPHS website.
•This project wants to rely on CPHS as the overseeing IRB of record for this multi-site project and (after the approval of the study by CPHS) they plan to submit amendment by attaching the fully signed reliance agreement form(s) (signed by their perspective IRBs and CPHS Chair) to document this agreement in the project application.

• Human Subjects: The study involves direct contacts with human subjects via recruitment from the CCR, focus groups, and interviews, with a primary focus on Black and Hispanic men, representing California's racial and socioeconomic diversity.

1. Qualitative Focus Groups: Conducted by NYU Langone, with diverse patients discussing pathology report terminology, particularly around "cancer" vs. "neoplasm/lesion."
2. One-on-One Interviews: Gather in-depth input on patient preferences for terminology and care options, which will inform a Discrete Choice Experiment (DCE).
3. Quantitative Survey: A DCE survey with 525 participants to explore how terminology and diagnosis labels impact patients' perceptions of treatment options.

Choose the CPHS Chair
Darci Delgado, PsyD

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

Assign to Cycle

December

Assign to cycle year
2024

Load into IRBManager (Initial Submission)
- Submitted 11/14/2024 7:35 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 11/14/2024 7:36 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2024-189

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

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• The project is aimed to evaluate patient perspectives on prostate cancer pathology terms through focus groups, interviews, and surveys, with data managed and housed at UCSF.
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3. Quantitative Survey: A DCE survey with 525 participants to explore how terminology and diagnosis labels impact patients' perceptions of treatment options.

Assign SME to study

Larry Dickey, MD, MPH, MSW

Enter the meeting date for this project

12/06/2024

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.

No answer provided.

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