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Award Number: W81XWH-09-1-0201

TITLE: Minorities in Clinical Trials: Patients, Physicians, Clinical Trial Characteristics,
and Their Environment

PRINCIPAL INVESTIGATOR: Celia P. Kaplan, DrPH, MA

CONTRACTING ORGANIZATION: University of California, San Francisco
San Francisco, CA 94118

REPORT DATE: July 2010

TYPE OF REPORT: Annual Report

PREPARED FOR: US Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01-07-2010		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 1 JUL 2009 - 30 JUN 2010	
4. TITLE AND SUBTITLE Minorities in Clinical Trials: Patients, Physicians, Clinical Trial Characteristics, and Their Environment				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-09-1-0201	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Celia P. Kaplan, DrPH, MA				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California—UCSF San Francisco, CA 94143-0962				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) Medical Research and Materiel Ft. Detrick, MD 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT In Year 01, the research team completed key research activities to lay the groundwork for data collection. These activities included: obtaining the appropriate approvals from Institutional Review Boards; identifying all eligible clinical trials, trial sites, and RTMs; finalizing the RTM Survey and completing the interviews, developing and examining the Patient Survey through semi-structured interviews; developing a preliminary draft of the Physician Survey; and obtaining the first half of the Registry patient data. No data analysis has been conducted at this time.					
15. SUBJECT TERMS Clinical trials, minorities, health care settings, communities					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 54	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	3
Reportable Outcomes.....	3
Conclusion.....	3
References.....	4
Appendices.....	5
<u>Appendix 1.</u> UCSF IRB (CHR) Approval	
<u>Appendix 2.</u> California State IRB (CPHS) Approval	
<u>Appendix 3.</u> Southern California CCR (CSP) Approval	
<u>Appendix 4.</u> Northern California CCR (NCCC) Approval	
<u>Appendix 5.</u> RTM Survey	
<u>Appendix 6.</u> Draft of Patient Interview	
<u>Appendix 7.</u> Draft of Physician Survey	

**Minorities in Clinical Trials: Patients, Physicians, Clinical
Trial Characteristics, and Their Environment (W81XWH-09-1-0201)**

Celia P. Kaplan, DrPH, MA, Principal Investigator

Annual Report 2010

Introduction

Our study will comprehensively examine the factors that facilitate or hinder participation in prostate cancer trials by examining patients' attitudes, physicians' perceived barriers, characteristics of prostate trials and sites, and broader community indicators. Synthesizing these multiple perspectives will facilitate the identification of deficits in the larger system of trial networks, and thus, inform system-wide interventions to increase minority participation in prostate cancer clinical trials.

Our main objectives are to: a) Conduct telephone interviews with 800 prostate cancer patients (Asian, Black, Latino, and White) identified through the CCR, who were treated at or reside within 60 miles of trial sites identified in objective to assess their discussions with physicians, intentions and actual participation in prostate cancer clinical trials, attitudes and knowledge about such trials, and barriers to and facilitators of participation, b) Conduct a self-administered survey of the physicians who care for, and were identified by the participating patients as their most influential physician, to determine their typical clinical trial counseling and referral practices, attitudes, and their perceived barriers to and facilitators of patient recruitment, c) Conduct a telephone survey with a research team member (RTM) from each prostate cancer clinical trial site within three regions of the California Cancer Registry (CCR) to assess its cultural competence and outreach efforts, and d) Identify and link clinical trial site community indicators to the clinical trial and patient data collected.

Body

The tasks described below represent the modified timeline and the progress made by the research team.

Task 1: Complete Human Subjects' Institutional Review. (Months 1-6)

Completed

We have submitted an application for review and received approval from the UCSF IRB, the Committee on Human Research (CHR). Through the course of our communication with the CCR we learned that our study had to also undergo formal review and approval by the California State IRB, the Committee for the Protection of Human Subjects (CPHS). We then had to submit a formal Application for Disclosure of Confidential Registry Data with each of the two regional registry agencies we were working with.

Task 2: Identify Clinical Trials (Months 1-6)

Completed

We have identified all 77 active prostate cancer clinical trials being conducted in 2008 in 10 California counties (Alameda, Contra Costa, Los Angeles, Marin, Monterey, San Benito, San Francisco, San Mateo, Santa Clara, and Santa Cruz) through cancer trial search engines. We have entered trial information into a Microsoft (MS) Access database.

Task 3: Characterize Clinical Trials and Trial Sites (Months 1-6)

Completed

Based on the information gathered in Task 2, we have entered characteristics of treatment and interventional prostate clinical trials and trial sites into the MS Access database. Clinical trial characteristics include the stage of trial, intervention type, and eligibility/exclusion criteria. Trial site characteristics include full addresses and facility type.

Task 4: Characterize Clinical Trial Sites and Research Team Members (RTM) (Months 3-14) **In Progress**

Based on the information gathered in Task 2 we have identified a RTM associated with each eligible clinical trial site. RTM information (e.g., name, telephone number, and e-mail address) has been entered into a MS Access database. The RTM online and telephone surveys have been developed based on existing surveys, literature, and discussions with the research team.

Surveys have been completed with 39 of the 58 RTMs identified at eligible sites. Data is being entered into an Access database. We continue to attempt to contact the remaining RTMs and are currently developing additional approach methods. We plan to finish the remaining RTM surveys in the next 3 months by conducting an in-depth follow-up protocol of the sites.

Task 5: Develop and Refine Instrument for the Patient Survey (Months 1-15) **In Progress**

A current draft of the patient telephone survey has been developed based on existing surveys, literature, and discussions among the research team.

Semi-structured interviews will be conducted with 12 prostate cancer patients (3 from each ethnic group under study) recruited at the urology cancer clinics at UCSF. At the time of this report, we have conducted 3 semi-structured interviews. We have experienced lower recruitment than anticipated, particularly among the minority populations.

Once in its final state, the survey will be translated into Spanish, Chinese and Tagalog. The patient survey will be cognitively pre-tested through interviews with eight participants. The pre-test will focus on the survey's clarity, consistency, and reliability. Revisions will be made accordingly. Following the cognitive pre-test, the patient survey will be tested again with eight additional respondents.

We expect to be finished with pre-testing and final survey development in the next 3 months.

Task 6: Identify Prostate Cancer Patients and their Attending Physicians (Month 3-16) **In Progress**

Patient information from the Northern CCR has been obtained and entered into a MS Access Database. This data includes all prostate cancer patients residing in the selected California counties. We have completed an agreement with the Southern CCR and expect the patient data from this registry soon. Patient information from the CCR includes the names and hospital affiliations of the patients' attending physicians. MS Access databases have been created to track patients' and physicians' information.

Due to the delays with the Southern CCR, we anticipate having all Patient and Attending Physician data in 4 months.

Task 7: Patient Recruitment and Survey Administration (Months 16-20) **To Be Completed**

Patients' physicians, as identified by CCR information, will be contacted to obtain approval for their patients' participation in the study. All patients who are not authorized by their physician to be contacted will not be included in the study. Physician consent or non-consent will be entered into the appropriate database.

Patients will receive a letter informing them about the study. Patients who do not refuse to participate will be contacted for phone interviews and their responses will be entered into a database.

Task 8: Develop and Refine Instrument for the Physician Survey (Months 6-14) **In Progress**

The current draft of the physician survey has been developed based on existing surveys, literature, and discussions with the research team. The survey will be pretested with six physicians. It will then be finalized, sent to the printer, and uploaded online for administration.

Task 9: Physician Recruitment and Survey Administration (Months 17-22) **To Be Completed**

During patient interviews (Task 7), participants will be asked for the names of the physicians who were the most influential in their treatment decisions. For patients who state that no physician was most influential in their treatment decisions, we will use the attending physician listed in the CCR database. Contact information for physicians identified as most influential will be obtained from the CCR Registry and the AMA Masterfile.

The physician surveys will be mailed to the physicians identified as most influential by their respective patients. The mailing will include a link to a study website where physicians can take the survey online. Non-responding physicians will be mailed a reminder postcard. A second survey will be mailed two months after the initial mailing. Responses to paper surveys will be entered into a database using the online survey.

Task 10: Identify Community Indicators (Months 12-16)

To Be Completed

Relevant community indicators will be identified based on the literature. Sources of publicly available geographic and demographic data will also be secured.

Data Analysis and Preparation of Final Reports (Months 20-24)

To Be Completed

Clinical trial sites and patient/physician addresses will be geocoded and preliminary analyses of survey and geocoded data will be performed. A final report and an initial manuscript draft will be prepared.

Key Research Accomplishments (Months 1-12)

- Completed Institutional, State, and Registry Human Subjects review submissions and approvals
- Obtained Patient Registry data from one of the two participating Registries
- Identified 77 eligible clinical trials
- Identified 58 eligible clinical trial sites
- Developed databases for Clinical Trials, Clinical Trial Sites, RTMs, Registry Patients, and Physicians
- Developed and finalized the RTM survey
- Developed preliminary versions of the Patient Phone Survey and the Physician Survey
- Completed 39 RTM surveys
- Completed 3 Patient Semi-structured Interviews

Reportable Outcomes

Not Applicable

Conclusion

In Year 01, the research team completed key research activities to lay the groundwork for data collection. These activities included: obtaining the appropriate approvals from Institutional Review Boards; identifying all eligible clinical trials, trial sites, and RTMs; finalizing the RTM Survey, developing and examining the Patient Survey through semi-structured interviews; developing a preliminary draft of the Physician Survey; and obtaining the first half of the Registry patient data.

We identified 77 prostate cancer treatment clinical trials in the selected counties active in 2008. The trials were conducted at 58 independent sites. Paper versions of the RTM Survey were mailed to a RTM at each of the sites. Two weeks later, they were contacted by phone to follow up on the survey status. To date, 39 surveys have been completed. Three sites have refused to participate and one site has stated they do not have a RTM available. The remaining 15 surveys will be completed in months 12-14 as we continue to attempt to contact alternative RTMs at each site. We are also exploring other methods of follow-up in order to maximize participation.

We have advertised the study among staff and patients in the urology oncology clinic at UCSF and have a research assistant onsite during busy clinic days to answer questions. To date, we have recruited 3 participants for semi-structured interviews to evaluate the Patient Survey. We will continue to recruit in this way and also submit a modification with our IRB to expand our recruitment procedures for the semi-structured interviews and for the cognitive pre-testing. The new recruitment procedures will match those of the main

study: we will identify patients from the CCR data who receive care from UCSF physicians, we will contact the physicians for permission to contact the patients, we will send a recruitment letter to the patients whose physicians consent, two weeks later we will follow-up with a phone call to invite them to participate.

Once we have completed the semi-structured interviews we will modify the Patient Survey based on participant feedback and discussion with the research team and proceed to cognitive pre-testing and then to data collection. The information obtained in the Patient Survey will allow us to proceed with the Physician Survey.

Though we faced some delays in the project this year, we have adapted our protocols to continue our activities and we look forward to beginning the data collection process. We will concentrate our efforts on the patient interviews and physician survey collection in the coming months in order to stay in line with our projected progress.

References

None

CHR APPROVAL LETTER

TO: Celia Patricia Kaplan, Dr.P.H., M.A.
Box 0856

Anna Napoles-Springer, M.P.H, Ph.D
Box 0856,

RE: Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and Their Environment

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents:

RTM Verbal Consent Form, Dated 4/7/09

Patient Verbal English Consent Form, Dated 10/13/09

Patient Information Sheet, Dated 1/2010

Patient Consent Form, Dated 1/2010

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

APPROVAL NUMBER: H9066-33779-02. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: February 24, 2010

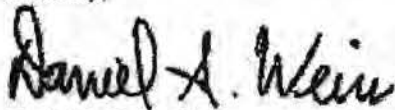
EXPIRATION DATE: March 10, 2011

Expedited Review

GENERAL CONDITIONS OF APPROVAL: Please refer to www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

HIPAA "Privacy Rule" (45CFR164) and Common Rule (45CFR46.116(d)): 1. This study has been granted a waiver of consent/authorization for access to Protected Health Information (PHI) for screening and/or recruitment purposes. 2. This study requires individual consent/authorization for use and/or disclosure of PHI for study enrollment.

Sincerely,



Daniel S. Weiss, Ph.D.
Vice Chair, Committee on Human Research

cc: Jessica Quinn, Box 0856

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 369
Sacramento, California 95811
(916) 326-3660 FAX (916) 322-2512



March 1, 2010

Celia P. Kaplan, DrPH, MA
UCSF
Box # 0856
San Francisco, CA 94143-0856

Project Title: "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment."

Project Number: 09-10-03

Dear Dr. Kaplan:

The Committee for the Protection of Human Subjects (CPHS), California Health and Human Services Agency, conducted an expedited review by a CPHS subcommittee of minor revisions to the above-entitled project in accordance with 45 CFR 46.110(b)(2). Please refer to the project title and project number listed above in future correspondence for this project.

The CPHS approved the following revisions provided with your letter dated February 8, 2010:

- Regarding Section 4 and Section 9.
- Changes made to Patient Consent Form, RTM Survey and new documents.

The due date for this project's renewal is **August 27, 2010** if this project is to continue beyond its expiration date of October 1, 2010. Since the CPHS' approval cannot exceed one year pursuant to 45 CFR 46.109(e), CPHS approval will be terminated on the expiration date above unless the CPHS has approved continuation. If CPHS has not approved this project by the renewal date, all research, including data analysis, must cease unless discontinuance will have an adverse impact on research subjects.

Also, if the project is completed or withdrawn it must be submitted to CPHS for approval. Please refer to the CPHS web site (www.oshpd.ca.gov/boards/cphs), "Instructions for Researchers", section V, for submission guidance and deadlines. Although CPHS sends courtesy reminders, it is the Principal Investigator's (PI) responsibility to submit the project renewal on time and to update the CPHS office on changes in the PI and Responsible Official contact information.

Research must be conducted according to the CPHS-approved proposal. CPHS review and approval are required before implementing any changes in your approved study except where necessary to eliminate apparent immediate hazards to human subjects. You are also responsible for the prompt reporting, within 48 hours, to the CPHS of any unanticipated problems or adverse events involving risks to human subjects and others.

If you have any questions, please contact our office at (916) 326-3660 or cphs-mail@oshpd.ca.gov.

Sincerely,

A handwritten signature in blue ink that reads "Joan M. Mock".

Joan M. Mock
Assistant Administrator



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

February 25, 2010

Ann Hamilton, PhD.
USC Norris Comprehensive Cancer Center
Keck School of Medicine
Department of Preventive Medicine
1441 Eastlake Ave., Rm. 3427, MC9175
Los Angeles, CA 90089-9175

Dear Dr. Hamilton:

Please find enclosed a copy of a signed approved agreement of disclosure of CCR data for Dr. Celia Kaplan's study with Region 9 of the CCR entitled "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment."

Sincerely,

Kurt P. Snipes, M.S., Ph.D., Chief
Cancer Surveillance and Research Branch

cc: Ann Brunson

Enclosure

Appendix 3: Confidentiality Agreement for Disclosure of CCR Data

The California Cancer Registry is a repository of cancer incidence data collected by the California Department of Public Health and regional cancer registries throughout the state of California from cancer reporting facilities and health-care providers under the authority of California Health and Safety Code section 103885. CCR data files contain medical and other personal information about identified individuals. By law, CCR data are confidential, and cannot be disclosed except in accordance with strict safeguards.

The University of California at San Francisco has applied to Los Angeles Cancer Surveillance Program for a copy of certain specified CCR data to be disclosed to Celia Kaplan, Dr. PH for the following proposed use: Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment (CSP #303).

In consideration for the CCR Data Custodian's disclosure of CCR data to Principal Investigator, Recipient Institution and Principal Investigator represent, warrant, and agree as follows:

1. For the purposes of this Confidentiality Agreement:

"Recipient Institution" means the unit of government, institution, agency, the corporation, or other entity that has requested CCR data, any other unit of government, institution, agency, corporation or other entity that owns or controls the recipient institution or of which the recipient institution is a constituent part, and the directors, officers, employees, consultants, volunteers, students, contractors, agents and associates of the recipient institution.

"Principal Investigator" means the individual that the recipient institution designated in its request to receive CCR data from the CCR, and who is principally responsible for undertaking the proposed use.

"CCR data" means all information relating to cases of cancer collected at any time by the California Department of Public Health, a regional cancer registry designated by the Department or any other individual or institution under the authority of California Health and Safety Code Section 103885 and predecessor statutes, whether or not such information identifies an individual or could be used to identify an individual. CCR data also means all documents, files or other records, regardless of format or medium, containing CCR data (whether alone or in combination with other data).

"Access to data " means the granting of the right to examine data.

"Disclosure of data" means the granting of the right to examine data and the right to create or retain a copy.

"Research" has the same definition as 45 CFR Section 46.102(d).

"Aggregate data" means statistical information derived from CCR data that does not include any individual item of data that represents a person, whether

identified, identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner.

"Reports and statistical information" means reports, articles, special analyses, studies, and other publications and communications that contain aggregate CCR data.

"Sources of information" means hospitals and other facilities or agencies providing diagnostic or treatment services to patients with cancer, and physicians, surgeons, dentists, podiatrists, and all other health care practitioners diagnosing or providing treatment for cancer patients, that have provided information contained in CCR data files.

2. California Health and Safety Code Section 103885 contains various provisions relating to use, access, disclosure, and publication of CCR data. These provisions may be different from the laws, regulations or policies applicable to other data used by Recipient Institution and Principal Investigator. Recipient Institution and Principal Investigator represent and warrant that: (a) they have reviewed section 103885, the California Department of Public Health, Cancer Surveillance and Research Branch, "Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry" (www.ccrca.org) (hereinafter "CCR Data Access and Disclosure Policies"), and the terms and conditions of this confidentiality agreement; (b) they have had a full opportunity to discuss any questions or concerns they may have regarding the interpretation of section 103885 and their duties and obligations under the statute and the terms and conditions of this confidentiality agreement with the CCR; (c) any such questions or concerns have been resolved to their satisfaction; and (d) on the basis of the foregoing review and discussions, they are prepared to receive and use CCR data in conformity with section 103885 and the terms and conditions of this confidentiality agreement.
3. Recipient Institution and Principal Investigator agree to comply with the requirements of California Health and Safety Code section 103885, any and all other federal and state laws or regulations relating to confidentiality, security, use, access, and disclosure of CCR data, and the CCR Data Access and Disclosure Policies.
4. Recipient Institution and Principal Investigator represent and warrant that the CCR data they have requested is necessary for the above-referenced proposed use. If Recipient Institution or Principal Investigator receives CCR data that are not necessary for the above-referenced proposed use, they will immediately notify CCR and destroy the unneeded CCR data.
5. Recipient Institution and Principal Investigator agree to use the requested CCR data in strict conformity with the proposed use set forth above. Recipient Institution and Principal Investigator agree not to use the CCR data for any other purpose, or for any purpose other than determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect, and they agree not to permit the CCR data to be used for any other purpose. Principal Investigator agrees to notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health if he or she becomes aware of errors

or omissions in the CCR data, or of patient vital statistics or address information that is more current than the CCR data provided to them under this agreement.

6. The Principal Investigator may have access to the CCR data. The Recipient Institution may grant access to the CCR data to other persons to carry out a specific assignment on behalf of the Recipient Institution, which is directly related to the use for which disclosure was granted. Persons seeking access must provide information sufficient to justify the request. The individual must sign an agreement to maintain the confidentiality of the data. Recipient Institution may use the CCR's Agreement for Access to CCR Data form (available at www.ccrca.org) or a comparable agreement for this purpose. Recipient Institution must maintain a list with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CCR data will be used. A copy of the list must be provided annually to the CCR Data Custodian. Except as provided in this paragraph, Recipient Institution agrees not to grant access to the CCR data to any person, nor shall it permit persons to whom it has granted access to authorize others to have access to the CCR data.
7. Except as expressly authorized by paragraph 9 of this Confidentiality Agreement, Recipient Institution and Principal Investigator agree not to disclose any part of the CCR data, whether or not it explicitly or implicitly identifies individuals, to any person or institution, not to copy or reproduce the CCR data in whole or in part (except as an institutional program of backup for disaster recovery or as a necessary condition of the research project), in any format or medium, and not to permit others to disclose or reproduce the CCR data. If Recipient Institution has a legitimate justification for sharing CCR data with another institution, e.g. as part of a collaborative research project, the Recipient Institution must obtain approval for this re-disclosure of the CCR data from the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.
8. Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody at the earliest opportunity consistent with the conduct of the proposed use unless there is a health or research justification for retention or retention is required by law. Notwithstanding the foregoing, Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody no later than three years after the date of receipt unless the CCR Data Custodian, in its sole discretion, extends the deadline for destruction by written notice to Recipient Institution and Principal Investigator. Destruction means physical destruction of files, documents or other records, and de-identification shall not be considered destruction. Immediately following the destruction of CCR data, Recipient Institution agree to provide the CCR Data Custodian with a written declaration, executed by an authorized representative of Recipient Institution, stating that the CCR data have been destroyed.
9. Recipient Institution and Principal Investigator may include aggregate data, conclusions drawn from studying CCR data, and case counts derived from CCR data such as incidence and mortality counts (provided that such case counts do not

in any way identify individual cases or sources of information) in professional journals, public reports, presentations, press releases and other publications. A copy shall be provided to the CCR Data Custodian and all publications shall contain the acknowledgement and disclaimer set forth in section VI.4. of the CCR Data Access and Disclosure Policies, and a copy shall be provided to the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

10. Recipient Institution and Principal Investigator shall not grant access to, disclose, admit, produce or otherwise make available any part of the CCR data in any civil, criminal, administrative, or other tribunal or court proceeding, whether voluntarily or under compulsion. Recipient Institution and Principal Investigator shall immediately notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health by telephone and fax of the receipt of any subpoena, discovery request, court order, search warrant or other form of compulsory legal process or threat of compulsory legal process in which CCR data and/or documents, data files or other materials containing CCR data are sought to be produced or examined. Recipient Institution shall immediately take all necessary legal action to oppose and resist any such compulsory legal process, e.g. file a motion to quash or written objections to a subpoena, or file written objections to a discovery request and opposition to a motion to compel.
11. If the proposed use is for research, Recipient Institution and Principal Investigator represent that they have obtained approval for the proposed use from the Recipient Institution's committee for the protection of human subjects established in accordance with part 46 (commencing with section 46.101) of title 45 of the Code of Federal Regulations, and that they will carry out the proposed use in accordance with such approval, except that the terms and conditions of this confidentiality agreement shall take precedence. Principal Investigator agrees to provide documentation of initial IRB approval and any renewals. If the proposed research involves patient contact based on information received from CCR, the Recipient Institution and Principal Investigator agree to follow the special requirements required by CCR for patient contact studies including approval for the proposed use from the California Committee for Protection of Human Subjects (Section V. 6. c. Policies and Procedures).
12. Recipient Institution represents that it has policies and procedures in effect consistent with the California Information Practices Act (California Civil Code Section 1798.24 and California Welfare and Institutions Code Section 10850) to maintain the security of the CCR data in its custody, including preventing unauthorized access, and further represents that it will maintain and enforce such policies and procedures at all times during which Recipient Institution has custody of CCR data.
13. Recipient Institution represents that it has policies and procedures in effect to implement and enforce its duties and obligations under this confidentiality agreement, and further represents that it will maintain and enforce such policies and procedures at all times during which it has custody of CCR data.

14. If Recipient Institution or Principal Investigator become aware of or reasonably suspect that any provision of this agreement has been violated, or that any circumstances exist which would prevent them from complying with their obligations under this agreement, they agree to immediately notify the CCR and take immediate steps to rectify the problem and prevent any recurrence.
15. This agreement creates a non-transferable limited license for Recipient Institution and Principal Investigator to use selected CCR data provided to them. Neither Recipient Institution nor Principal Investigator shall acquire any ownership, title or other interest in any CCR data or any copy of CCR data provided to them.
16. Recipient Institution agrees to indemnify, defend and hold harmless the State of California and the CCR Data Custodian and their respective agencies, officers, directors, employees and agents from and against any and all claims, losses, damages, costs, expenses or other liability, including attorney fees and expenses, arising out of or related directly or indirectly to Recipient Institution and Principal Investigator's receipt of CCR data.
17. The CCR Data Custodian reserves the right to terminate Recipient Institution and Principal Investigator's custody of CCR data by written notice at any time without cause. Upon receipt of such notice, Recipient Institution shall immediately and permanently destroy all copies of CCR data in its custody.
18. Recipient Institution and Principal Investigator acknowledge that if they fail to comply with any of their obligations under this confidentiality agreement, the CCR Data Custodian and the State of California will suffer immediate, irreparable harm for which monetary damages will not be adequate. Recipient Institution and Principal Investigator agree that, in addition to any other remedies provided at law or in equity, the CCR Data Custodian and/or the State of California shall be entitled to injunctive relief to enforce the provisions of this agreement.
19. This is the entire agreement between the parties. It supersedes all prior oral or written agreements or understandings and it may be amended only in writing. This agreement, and the rights created hereunder, are individual and not assignable or otherwise transferable by Recipient Institution or Principal Investigator. This agreement is entered into for the benefit of the State of California, which shall have the right to enforce this agreement. This agreement and any dispute arising under this agreement shall be governed by the laws of the State of California. This agreement and the representations and covenants contained herein shall survive the expiration or termination of Recipient Institution and/or Principal Investigator's right to custody of CCR data. Any dispute that arises under or relates to this agreement shall be resolved in the State of California, Superior Court for the county in which the CCR Data custodian is located or, at the option of the State of California, Sacramento County Superior Court. In any litigation or other proceeding by which one party seeks to enforce its rights under this agreement or seeks a declaration of any rights or obligations under this agreement, the prevailing party shall be awarded reasonable attorney fees, together with any costs and expenses, to resolve the dispute and to enforce the final judgment.

20. Notwithstanding any other provision of this agreement, the CCR Data Custodian shall have no obligation to provide CCR data to Recipient Institution and Principal Investigator unless and until this agreement is approved by the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

For Recipient Institution:

I have read the foregoing agreement. I have the authority to execute this confidentiality agreement on behalf of the Recipient Institution. By signing below I make the agreements, and representations contained therein on behalf of the Recipient Institution. I understand that these are material representations of fact upon which reliance was placed when this transaction was entered into.

Elisa J. Perez-Sastre MD 11/10/2009
Signature Dated

Elisa J Perez-Sastre MD Chief Division of General Internal
Printed Name and Title Med, UL, no beta

Principal Investigator:

I have read the foregoing agreement. By signing below I make the agreements and representations contained therein. I understand that these material representations of fact upon which reliance was placed when this transaction was entered into.

Celia Kaplan 4/04/09
Signature Dated

Celia Kaplan, Associate Professor.
Printed Name and Title

APPROVAL BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CANCER SURVEILLANCE AND RESEARCH BRANCH:

Kurt Snipes 3/1/10
Signature Dated

KURT SNIPEs, CHIEF CSRB
Printed Name and Title

RDC
2/24/2010



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

February 11, 2010

Kari Fish
Northern California Cancer Center
2201 Walnut Ave., Suite 300
Freemont, CA 94538

Dear Ms. Fish:

Please find enclosed a copy of a signed approved agreement of disclosure of CCR data for Dr. Celia Kaplan's study with Region 1/8 of the CCR entitled "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment."

Sincerely,

Kurt P. Snipes, M.S., Ph.D., Chief
Cancer Surveillance and Research Branch

cc: Ann Brunson

Enclosure

Appendix 3: Confidentiality Agreement for Disclosure of CCR Data

The California Cancer Registry is a repository of cancer incidence data collected by the California Department of Public Health and regional cancer registries throughout the state of California from cancer reporting facilities and health-care providers under the authority of California Health and Safety Code section 103885. CCR data files contain medical and other personal information about identified individuals. By law, CCR data are confidential, and cannot be disclosed except in accordance with strict safeguards.

The University of California at San Francisco has applied to The Northern California Cancer Center for a copy of certain specified CCR data to be disclosed to Celia Kaplan, DrPH for the following proposed use: Study entitled "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment".

In consideration for the CCR Data Custodian's disclosure of CCR data to Principal Investigator, Recipient Institution and Principal Investigator represent, warrant, and agree as follows:

1. For the purposes of this Confidentiality Agreement:

"Recipient Institution" means the unit of government, institution, agency, the corporation, or other entity that has requested CCR data, any other unit of government, institution, agency, corporation or other entity that owns or controls the recipient institution or of which the recipient institution is a constituent part, and the directors, officers, employees, consultants, volunteers, students, contractors, agents and associates of the recipient institution.

"Principal Investigator" means the individual that the recipient institution designated in its request to receive CCR data from the CCR, and who is principally responsible for undertaking the proposed use.

"CCR data" means all information relating to cases of cancer collected at any time by the California Department of Public Health, a regional cancer registry designated by the Department or any other individual or institution under the authority of California Health and Safety Code Section 103885 and predecessor statutes, whether or not such information identifies an individual or could be used to identify an individual. CCR data also means all documents, files or other records, regardless of format or medium, containing CCR data (whether alone or in combination with other data).

"Access to data" means the granting of the right to examine data.

"Disclosure of data" means the granting of the right to examine data and the right to create or retain a copy.

"Research" has the same definition as 45 CFR Section 46.102(d).

"Aggregate data" means statistical information derived from CCR data that does not include any individual item of data that represents a person, whether

identified, identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner.

"Reports and statistical information" means reports, articles, special analyses, studies, and other publications and communications that contain aggregate CCR data.

"Sources of information" means hospitals and other facilities or agencies providing diagnostic or treatment services to patients with cancer, and physicians, surgeons, dentists, podiatrists, and all other health care practitioners diagnosing or providing treatment for cancer patients, that have provided information contained in CCR data files.

2. California Health and Safety Code Section 103885 contains various provisions relating to use, access, disclosure, and publication of CCR data. These provisions may be different from the laws, regulations or policies applicable to other data used by Recipient Institution and Principal Investigator. Recipient Institution and Principal Investigator represent and warrant that: (a) they have reviewed section 103885, the California Department of Public Health, Cancer Surveillance and Research Branch, "Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry" (www.ccrca.org) (hereinafter "CCR Data Access and Disclosure Policies"), and the terms and conditions of this confidentiality agreement; (b) they have had a full opportunity to discuss any questions or concerns they may have regarding the interpretation of section 103885 and their duties and obligations under the statute and the terms and conditions of this confidentiality agreement with the CCR; (c) any such questions or concerns have been resolved to their satisfaction; and (d) on the basis of the foregoing review and discussions, they are prepared to receive and use CCR data in conformity with section 103885 and the terms and conditions of this confidentiality agreement.
3. Recipient Institution and Principal Investigator agree to comply with the requirements of California Health and Safety Code section 103885, any and all other federal and state laws or regulations relating to confidentiality, security, use, access, and disclosure of CCR data, and the CCR Data Access and Disclosure Policies.
4. Recipient Institution and Principal Investigator represent and warrant that the CCR data they have requested is necessary for the above-referenced proposed use. If Recipient Institution or Principal Investigator receives CCR data that are not necessary for the above-referenced proposed use, they will immediately notify CCR and destroy the unneeded CCR data.
5. Recipient Institution and Principal Investigator agree to use the requested CCR data in strict conformity with the proposed use set forth above. Recipient Institution and Principal Investigator agree not to use the CCR data for any other purpose, or for any purpose other than determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect, and they agree not to permit the CCR data to be used for any other purpose. Principal Investigator agrees to notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health if he or she becomes aware of errors

or omissions in the CCR data, or of patient vital statistics or address information that is more current than the CCR data provided to them under this agreement.

6. The Principal Investigator may have access to the CCR data. The Recipient Institution may grant access to the CCR data to other persons to carry out a specific assignment on behalf of the Recipient Institution, which is directly related to the use for which disclosure was granted. Persons seeking access must provide information sufficient to justify the request. The individual must sign an agreement to maintain the confidentiality of the data. Recipient Institution may use the CCR's Agreement for Access to CCR Data form (available at www.ccrca.org) or a comparable agreement for this purpose. Recipient Institution must maintain a list with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CCR data will be used. A copy of the list must be provided annually to the CCR Data Custodian. Except as provided in this paragraph, Recipient Institution agrees not to grant access to the CCR data to any person, nor shall it permit persons to whom it has granted access to authorize others to have access to the CCR data.
7. Except as expressly authorized by paragraph 9 of this Confidentiality Agreement, Recipient Institution and Principal Investigator agree not to disclose any part of the CCR data, whether or not it explicitly or implicitly identifies individuals, to any person or institution, not to copy or reproduce the CCR data in whole or in part (except as an institutional program of backup for disaster recovery or as a necessary condition of the research project), in any format or medium, and not to permit others to disclose or reproduce the CCR data. If Recipient Institution has a legitimate justification for sharing CCR data with another institution, e.g. as part of a collaborative research project, the Recipient Institution must obtain approval for this re-disclosure of the CCR data from the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.
8. Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody at the earliest opportunity consistent with the conduct of the proposed use unless there is a health or research justification for retention or retention is required by law. Notwithstanding the foregoing, Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody no later than three years after the date of receipt unless the CCR Data Custodian, in its sole discretion, extends the deadline for destruction by written notice to Recipient Institution and Principal Investigator. Destruction means physical destruction of files, documents or other records, and de-identification shall not be considered destruction. Immediately following the destruction of CCR data, Recipient Institution agree to provide the CCR Data Custodian with a written declaration, executed by an authorized representative of Recipient Institution, stating that the CCR data have been destroyed.
9. Recipient Institution and Principal Investigator may include aggregate data, conclusions drawn from studying CCR data, and case counts derived from CCR data such as incidence and mortality counts (provided that such case counts do not

in any way identify individual cases or sources of information) in professional journals, public reports, presentations, press releases and other publications. A copy shall be provided to the CCR Data Custodian and all publications shall contain the acknowledgement and disclaimer set forth in section VI.4. of the CCR Data Access and Disclosure Policies, and a copy shall be provided to the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

10. Recipient Institution and Principal Investigator shall not grant access to, disclose, admit, produce or otherwise make available any part of the CCR data in any civil, criminal, administrative, or other tribunal or court proceeding, whether voluntarily or under compulsion. Recipient Institution and Principal Investigator shall immediately notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health by telephone and fax of the receipt of any subpoena, discovery request, court order, search warrant or other form of compulsory legal process or threat of compulsory legal process in which CCR data and/or documents, data files or other materials containing CCR data are sought to be produced or examined. Recipient Institution shall immediately take all necessary legal action to oppose and resist any such compulsory legal process, e.g. file a motion to quash or written objections to a subpoena, or file written objections to a discovery request and opposition to a motion to compel.
11. If the proposed use is for research, Recipient Institution and Principal Investigator represent that they have obtained approval for the proposed use from the Recipient Institution's committee for the protection of human subjects established in accordance with part 46 (commencing with section 46.101) of title 45 of the Code of Federal Regulations, and that they will carry out the proposed use in accordance with such approval, except that the terms and conditions of this confidentiality agreement shall take precedence. Principal Investigator agrees to provide documentation of initial IRB approval and any renewals. If the proposed research involves patient contact based on information received from CCR, the Recipient Institution and Principal Investigator agree to follow the special requirements required by CCR for patient contact studies including approval for the proposed use from the California Committee for Protection of Human Subjects (Section V. 6. c. Policies and Procedures).
12. Recipient Institution represents that it has policies and procedures in effect consistent with the California Information Practices Act (California Civil Code Section 1798.24 and California Welfare and Institutions Code Section 10850) to maintain the security of the CCR data in its custody, including preventing unauthorized access, and further represents that it will maintain and enforce such policies and procedures at all times during which Recipient Institution has custody of CCR data.
13. Recipient Institution represents that it has policies and procedures in effect to implement and enforce its duties and obligations under this confidentiality agreement, and further represents that it will maintain and enforce such policies and procedures at all times during which it has custody of CCR data.

14. If Recipient Institution or Principal Investigator become aware of or reasonably suspect that any provision of this agreement has been violated, or that any circumstances exist which would prevent them from complying with their obligations under this agreement, they agree to immediately notify the CCR and take immediate steps to rectify the problem and prevent any recurrence.
15. This agreement creates a non-transferable limited license for Recipient Institution and Principal Investigator to use selected CCR data provided to them. Neither Recipient Institution nor Principal Investigator shall acquire any ownership, title or other interest in any CCR data or any copy of CCR data provided to them.
16. Recipient Institution agrees to indemnify, defend and hold harmless the State of California and the CCR Data Custodian and their respective agencies, officers, directors, employees and agents from and against any and all claims, losses, damages, costs, expenses or other liability, including attorney fees and expenses, arising out of or related directly or indirectly to Recipient Institution and Principal Investigator's receipt of CCR data.
17. The CCR Data Custodian reserves the right to terminate Recipient Institution and Principal Investigator's custody of CCR data by written notice at any time without cause. Upon receipt of such notice, Recipient Institution shall immediately and permanently destroy all copies of CCR data in its custody.
18. Recipient Institution and Principal Investigator acknowledge that if they fail to comply with any of their obligations under this confidentiality agreement, the CCR Data Custodian and the State of California will suffer immediate, irreparable harm for which monetary damages will not be adequate. Recipient Institution and Principal Investigator agree that, in addition to any other remedies provided at law or in equity, the CCR Data Custodian and/or the State of California shall be entitled to injunctive relief to enforce the provisions of this agreement.
19. This is the entire agreement between the parties. It supersedes all prior oral or written agreements or understandings and it may be amended only in writing. This agreement, and the rights created hereunder, are individual and not assignable or otherwise transferable by Recipient Institution or Principal Investigator. This agreement is entered into for the benefit of the State of California, which shall have the right to enforce this agreement. This agreement and any dispute arising under this agreement shall be governed by the laws of the State of California. This agreement and the representations and covenants contained herein shall survive the expiration or termination of Recipient Institution and/or Principal Investigator's right to custody of CCR data. Any dispute that arises under or relates to this agreement shall be resolved in the State of California, Superior Court for the county in which the CCR Data custodian is located or, at the option of the State of California, Sacramento County Superior Court. In any litigation or other proceeding by which one party seeks to enforce its rights under this agreement or seeks a declaration of any rights or obligations under this agreement, the prevailing party shall be awarded reasonable attorney fees, together with any costs and expenses, to resolve the dispute and to enforce the final judgment.

20. Notwithstanding any other provision of this agreement, the CCR Data Custodian shall have no obligation to provide CCR data to Recipient Institution and Principal Investigator unless and until this agreement is approved by the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

For Recipient Institution:

I have read the foregoing agreement. I have the authority to execute this confidentiality agreement on behalf of the Recipient Institution. By signing below I make the agreements, and representations contained therein on behalf of the Recipient Institution. I understand that these are material representations of fact upon which reliance was placed when this transaction was entered into.

Elise J Perez-Sastre MD 11/10/2009
Signature Dated
Elise J Perez-Sastre MD Chief Division of General Internal
Printed Name and Title Med, UCL, no bene

Principal Investigator:

I have read the foregoing agreement. By signing below I make the agreements and representations contained therein. I understand that these material representations of fact upon which reliance was placed when this transaction was entered into.

Celia Kaplan 11/04/09
Signature Dated
Celia Kaplan, Associate Professor.
Printed Name and Title

APPROVAL BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CANCER SURVEILLANCE AND RESEARCH BRANCH:

Kwame Snipes 2/11/10
Signature Dated
CHIEF, CSRB KWAME SNIPES
Printed Name and Title

RDC
2/10/2010

RTM ID: _____

Site ID: _____

Date: ____/____/____

Initials: _____

PROSTATE CANCER RESEARCH TEAM MEMBER SURVEY

Thank you for taking the time to complete our survey about participation in prostate cancer trials. This study is funded by the Prostate Cancer Research Program as part of the Department of Defense Congressionally Directed Medical Research Program. It should take about 10 minutes to complete. Your experiences and insights will help us better understand the issues patients face when considering participation in trials.

Your answers will be kept completely confidential. Your name and the name of your organization will never be used in publications or written data results. Information that can identify you and your organization will not be shared with any third party and will be stored separately from your responses. Your participation in the survey is voluntary and you may discontinue participation at any time without penalty.

1. What is your gender? Female ☐₁ Male ☐₂
2. Where were you born? United States ☐₁ Another country ☐₂ → Please specify: _____
3. What is the highest educational level you have attained? Please choose only one.

High school, secondary school, GED or equivalent	☐ ₁
Some college, trade school, vocational school or Associate's degree	☐ ₂
Bachelor's degree	☐ ₃
Graduate school	☐ ₄
4. Do you have a nursing degree? No ☐₀ Yes ☐₁ → 5. Are you a Registered Nurse? No ☐₀ Yes ☐₁
6. Which of the following departments do you **primarily** work with? Please choose only one.

Urology	☐ ₁
Medical Oncology/Hematology Oncology	☐ ₂
Radiation Oncology	☐ ₃
Primary Care	☐ ₄
Other department	☐ ₅ → Please specify: _____
7. How long have you been involved in research? ____ Years ____ Months
8. What is your job title? _____
9. Which of the following describe your duties **related to prostate cancer trials** at your organization?

a. Lead a research team as PI or Co-Investigator	☐	f. Manage research data	☐
b. Direct/Lead/Manage a clinical research program	☐	g. Conduct clinical tests or procedures on patients	☐
c. Coordinate the day-to-day non-clinical research operations	☐	h. Maintain regulatory documents	☐
d. Enroll participants	☐	i. General office/admin duties	☐
e. Coordinate and schedule participant visits	☐	j. Other duties	☐

↳ Specify: _____

10. In the past year, what proportion of the **prostate cancer patients** treated at your organization participated in **prostate cancer trials**? *Please give your best estimate.*

All	Almost All	Some	Almost None	None
☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

11. In the past year, approximately what percent of your **prostate cancer trial participants**...? *Give your best estimate.*

- a. were uninsured? _____%
- b. were covered by Medi-Cal / Medicaid? _____%
- c. needed a language interpreter to receive services? _____%

12. In the past year, what percent of your **prostate cancer trial participants** belonged to the following racial/ethnic groups? *Please give your best estimate.*

- a. Black/African American _____%
- b. Asian or Pacific Islander _____%
- c. Hispanic/Latino _____%

13. What is the ethnic composition of your **prostate cancer trial research team** (including yourself, investigators, nurses, coordinators, and administrators)? *Please give your best estimate.*

- a. Black/African American _____%
- b. Asian or Pacific Islander _____%
- c. Hispanic/Latino _____%

14. Does anyone on the **prostate cancer trial team** (including yourself) speak a language other than English well enough to obtain informed consent from study participants?

No ☐₀ *Proceed to question 16*

Yes ☐₁ → 15. Which languages do they speak?

Mark all that apply.

- a. Spanish ☐
- b. Chinese ☐
- c. Vietnamese ☐
- d. Tagalog ☐
- e. Other language(s) ☐

↳ *Please specify:* _____

16. In the past year, how often did your organization offer the following types of language interpretation to **prostate cancer patients** at the time of **enrollment** in a cancer trial?

	Always	Sometimes	Never
a. Non-professional interpretation by bilingual staff	☐ ₁	☐ ₂	☐ ₃
b. Professional language interpretation onsite	☐ ₁	☐ ₂	☐ ₃
c. Professional language interpretation by telephone	☐ ₁	☐ ₂	☐ ₃
d. Professional language interpretation by internet/video	☐ ₁	☐ ₂	☐ ₃
e. Other types, <i>please specify:</i> _____	☐ ₁	☐ ₂	☐ ₃

17. For which of the following languages does your organization provide **professional** (onsite, by phone, or by video) interpreter services for **prostate cancer trial participants**? *Please mark all that apply.*

- a. All Languages (e.g. AT&T Language Line) ☐
- b. Spanish ☐
- c. Chinese ☐
- d. Vietnamese ☐
- e. Tagalog ☐
- f. Other language(s) ☐ → *Please specify:* _____

18. Which of the following printed materials are available to your **prostate cancer trial participants**?

- a. Consent Forms ☐
- b. "Short Form" Consent Forms ☐
- c. Experimental Subjects' Bill of Rights ☐
- d. Summaries of trials ☐
- e. Frequently asked questions (FAQ) sheet about the studies ☐
- f. Directions to study site ☐
- g. Appointment reminder cards ☐
- h. Study fliers or posters ☐

19. Which of the following printed materials are available to your **prostate cancer trial participants** in a language **other than English**?

- a. Consent Forms ☐
- b. "Short Form" Consent Forms ☐
- c. Experimental Subjects' Bill of Rights ☐
- d. Summaries of trials ☐
- e. Frequently asked questions (FAQ) sheet about the studies ☐
- f. Directions to study site ☐
- g. Appointment reminder cards ☐
- h. Study fliers or posters ☐

20. In the past year, which of the following methods has your organization used to recruit participants to **prostate cancer trials**? *Please mark all that apply.*

- a. Recruitment videos or CDs ☐
- b. Recruitment advertisements in local newspapers ☐
- c. A dedicated phone line to receive patient inquiries about the cancer trials ☐
- d. Presentations about the trials to community groups and churches ☐
- e. Presentations to health providers **within your organization** *including Tumor Boards and Conferences* ☐
- f. Presentations to health providers **outside your organization** ☐
- g. Distributing trial information at community health fairs or cancer awareness days ☐
- h. Posting the trials on your hospital/organization's website ☐
- i. Other activities, *please specify:* _____ ☐

21. In the past year, which of the following incentives has your organization provided to your **prostate cancer trial participants**? *If no incentives provided, please mark 'Not provided'.*

	For <u>all</u> participants	For <u>some</u> participants	Not provided
a. Complimentary or valet parking	☐ ₁	☐ ₂	☐ ₃
b. Help with transportation (e.g. bus tickets or taxi vouchers)	☐ ₁	☐ ₂	☐ ₃
c. Cash or gift cards/certificates	☐ ₁	☐ ₂	☐ ₃
d. Complimentary food or beverages	☐ ₁	☐ ₂	☐ ₃
e. Sponsor-provided gifts (e.g., mugs, pencils, t-shirts)	☐ ₁	☐ ₂	☐ ₃
f. Other incentive(s), <i>please specify</i> : _____	☐ ₁	☐ ₂	☐ ₃

22. Below is a list of factors that may be barriers for **patients** to participate in **prostate cancer trials**. Please indicate if you think each factor is a major barrier, a moderate barrier, a minor barrier, or not a **barrier for patients**.

Patients...	Major Barrier	Moderate Barrier	Minor Barrier	Not a Barrier
a. are concerned that the risks outweigh the benefits.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
b. are concerned that the trials cannot accommodate non-English speakers.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
c. don't understand what clinical trials are.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
d. lack adequate insurance coverage.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
e. don't meet the eligibility or study entry criteria.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
f. lack transportation.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
g. are reluctant to complete paperwork.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
h. are unable to take time from work, family, or other duties.	☐ ₁	☐ ₂	☐ ₃	☐ ₄

23. Below is a list of factors that may be barriers for **physicians** to refer or enroll their patients for **prostate cancer trials**. Please indicate if you think each factor is a major barrier, a moderate barrier, a minor barrier, or not a **barrier for physicians**.

Physicians...	Major Barrier	Moderate Barrier	Minor Barrier	Not a Barrier
a. are concerned that the trial treatment will be inferior to standard treatments.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
b. are concerned that patients referred to trials will not return to their practice.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
c. are concerned about the time and effort required to explain trials to the patient.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
d. are concerned about inadequate reimbursement from research sponsors.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
e. don't have adequate time dedicated for research.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
f. don't have adequate information about the trials.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
g. are concerned that patients will not adhere with the study protocol.	☐ ₁	☐ ₂	☐ ₃	☐ ₄

Thank you for completing the survey! Please email, fax, or mail this survey to:

Maya Yoshida - Research Coordinator
Mail: UCSFBox 0856 / San Francisco Ca 94143-0856
Fax: 415-502-8291
Email: myoshida@medicine.ucsf.edu
Phone: 1-888-663-6661

DOD Prostate: Patient Interview

CASE ID#	Patient ID	Interviewer	Today's Date / /	Language

Hello, my name is []. I'm calling from the University of California, San Francisco. May I speak with [], please?

RESPONDENT ON PHONE	1	CONTINUE
RESPONDENT NOT AVAILABLE	2	When would be a good time to call back? _____. Thanks for your time. Have a nice day/evening. END CALL.
RESPONDENT NOT AT THIS NUMBER	3	Do you know how I can reach him? _____. Thanks for your time. Have a nice day/afternoon/evening. END CALL.

IF APPLICABLE: Which language would you prefer to speak in?

ENGLISH	1	READ NEXT SECTION IN ENGLISH
SPANISH	2	READ NEXT SECTION IN SPANISH
CANTONESE	3	READ NEXT SECTION IN CANTONESE
TAGALOG	4	READ NEXT SECTION IN TAGALOG
NONE /OTHER		CONTINUE

IF NONE/OTHER LANGUAGE: Would you feel comfortable answering questions about your health in one of the following four languages?

	YES	NO	
English	1	2	CONTINUE IN ENGLISH
Spanish	1	2	CONTINUE IN SPANISH
Cantonese	1	2	CONTINUE IN CANTONESE
Tagalog	1	2	CONTINUE IN TAGALOG
NONE /OTHER			I'm sorry; we can only do this survey in English, Spanish, Cantonese, or Tagalog. Thank you for your time and have a nice day/afternoon/evening. END CALL.

I'm calling to follow up on a letter that our research group sent you recently. This letter described a research study that Dr. Celia Kaplan is conducting at the UCSF Department of Medicine. In this study, we hope to learn about why people decide to participate or not participate in clinical trials. Clinical trials are research studies that involve people and test new ways to prevent, detect, diagnose, and treat diseases such as cancer. This project is funded by the Prostate Cancer Research Program which is one of the Department of Defense Congressionally Directed Medical Research Programs. We are asking you to participate in a 30-minute interview. We will be asking you questions related to what you know and think about cancer clinical trials. We will also ask about your cancer diagnosis and some background questions about yourself. We will use this information to help increase participation in prostate cancer clinical trials.

Would you like to participate in this study?

NO

That's fine. Thanks so much for your time and have a nice day/afternoon/evening. END CALL.

MAYBE—[IF CAN'T DECIDE / WANTS MORE INFO]

OFFER TO RESEND LETTER & INFO SHEET OR PROVIDE CELIA'S INFORMATION.

SCHEDULE A TIME TO CALL BACK: _____

DR. CELIA KAPLAN
(415) 502-5601

CELIA.KAPLAN@UCSF.EDU

END CALL.

UCSF

BOX 0856

SAN FRANCISCO, CA 94143

YES—INITIAL BELOW AND CONTINUE

That's great, thank you! Is this a good time to do the interview?

YES	1	CONTINUE
NO, LATER	2	When would be a good time to call back? _____ ____ thanks for your time, and I'll be speaking with you on _____. Have a nice day/afternoon/evening. END CALL.

[CONSENT]

After the interview, we will send you a \$10.00 gift card as a thank you for your time and participation. Your name, answers, and study records will be kept confidential. However, representatives of the committees on Human Research at UCSF and the US Department of Defense are eligible to review your research records as a part of their responsibility to protect human volunteers in research.

Your participation is entirely voluntary and will not affect your health care or health insurance in any way. You can refuse to participate without consequences. If you do decide to participate, you are free to skip any questions that you do not feel comfortable answering, and you may stop the interview at any time.

Shall we begin?

INITIALS		DATE	
----------	--	------	--

DEMOGRAPHICS

I'd like to begin by asking you some questions about yourself.

1. How old are you? _____

2. Would you describe yourself as...?

White or Caucasian	1	GO TO # 4	
Hispanic or Latino	2	GO TO # 4	
Black or African-American	3	GO TO # 4	
Asian-American	4	GO TO # 4	
Other ethnicity	6	CONTINUE	
2a. OTHER SPECIFY: _____			**Check list
MORE THAN ONE GROUP	7	CONTINUE	
DK	77	CONTINUE	
REF	99	*INELIGIBLE	Thank you for your time and have a nice day/afternoon/evening.

3. [IF MORE THAN ONE GROUP OR DK] With which race or ethnicity do you identify the most?

WHITE OR CAUCASIAN	1	CONTINUE	
HISPANIC OR LATINO	2	CONTINUE	
BLACK OR AFRICAN-AMERICAN	3	CONTINUE	
ASIAN-AMERICAN	4	CONTINUE	
OTHER ETHNICITY	6	CONTINUE	**Check list
3a. OTHER SPECIFY: _____			
REF	99	INELIGIBLE*	Thank you for your time and have a nice day/afternoon/evening.

LANGUAGE & HEALTH

4. Is English your first language?¹

YES	1	GO TO # 7
NO	0	CONTINUE
DK	77	
REF	99	

5. What is your first language?

SPANISH	1	CONTINUE
CANTONESE	2	CONTINUE
TAGALOG	3	CONTINUE
OTHER	4	* INELIGIBLE
5a. OTHER SPECIFY _____		

6. How well do you speak English? Would you say...?¹

Very Well	1	CONTINUE
Well	2	CONTINUE
So, so	3	**PARTICIPANT IS LEP**
Poorly	4	**PARTICIPANT IS LEP**
Not at all	5	**PARTICIPANT IS LEP**
DK	77	
REF	99	

7. Overall, how would you rate your health? Would you say it is....

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
DK	77
REF	99

DIAGNOSIS & TREATMENT

Now I would like to learn about your prostate cancer diagnosis and treatment.

8. When was your prostate cancer first diagnosed?² PROBE: DO YOU REMEMBER THE MONTH & YEAR?

MONTH	____
YEAR	____
DK	77
REF	99

9. Please take a moment to think about the different tests you took, which led to the biopsy that diagnosed your prostate cancer.²

		YES	NO	DK	REF
a.	Did you have a PSA test that led to the biopsy that diagnosed your prostate cancer? This is a blood sample for prostate cancer.	1	0	77	99
b.	Did you have a Digital Rectal Exam (DRE) that led to the biopsy that diagnosed your cancer? This is when the doctor checks the prostate with a finger through the anus to feel the surface of the prostate.	1	0	77	99
c.	Was your prostate cancer diagnosed some other way?	1	0	77	99
	c1. OTHER SPECIFY: _____				

10. Do you remember your....²

		YES	NO	DK	NA	REF		11. What was it?
a.	PSA level at the time of your diagnosis?	1	0	77	88	99	IF YES →	a. _____
b.	Gleason Score at the time of your diagnosis? A Gleason score is from a biopsy and tells ...the aggressiveness of the tumor. OR ...how likely the tumor is to spread. (NCI)	1	0	77	88	99	IF YES →	b. _____
c.	Cancer stage at the time of your diagnosis? This is a number that classifies the ...how much the cancer has already spread in the body OR ...how much cancer is currently there in the body.	1	0	77	88	99	IF YES →	c. _____

12. What treatments did you receive for your prostate cancer?²⁻⁵ [MARK ALL THAT APPLY]

	Did you receive...	YES	NO
a.	Watchful waiting? This is when your doctor closely monitors your condition without treatment, until symptoms or blood test results change.	1	0
b.	Surgery? A doctor removes the prostate in an operation.	1	0
c.	Radiation therapy? This is when a patient receives direct radioactive beams (such as X-ray) to kill the prostate cancer cells over the course of weeks.	1	0
d.	Seed implants? This is a onetime procedure where a doctor uses a needle to put tiny radioactive seeds directly into the prostate cancer cells to kill them.	1	0
e.	Hormone therapy? This is when a doctor uses hormones, usually a pill or a shot, to stop prostate cancer cells from growing over the course of years.	1	0
f.	Chemotherapy? This is when a doctor uses medications, usually given through the vein, to kill prostate cancer cells over a course of weeks or months.	1	0
g.	Any other treatment?	1	0
	g1. OTHER SPECIFY: _____		
		DK	77
		REF	99

13. Has a doctor ever told you that you had any of the following health conditions?²

		YES	NO	DK	REF
a.	Diabetes	1	0	77	99
b.	Depression	1	0	77	99
c.	Heart problems	1	0	77	99
d.	Arthritis	1	0	77	99
e.	Other cancer	1	0	77	99
	e1. OTHER CANCER SPECIFY: _____				
f.	Other health conditions	1	0	77	99
	f1. OTHER SPECIFY: _____				

PATIENT'S ATTENDING PHYSICIANS

Now we would like to learn about the doctors you saw for your prostate cancer. Please take a moment to think about all the doctors you talked to about your diagnosis and treatment.

CHECK COVERSHEET FOR NAME OF PHYSICIAN:

2 PATHWAYS TO DETERMINE THE PATIENT'S ATTENDING PHYSICIANS:

- A. IF THE PHYSICIAN IS LISTED IN THE DATABASE
- B. IF THE PHYSICIAN IS NOT LISTED IN THE DATABASE

MUST OBTAIN AT LEAST 2 PHYSICIANS' CONTACT INFORMATION FOR THE PHYSICIAN SURVEY

PATH A: IF THE PHYSICIAN(S) IS LISTED IN THE DATABASE

14. Our records indicate that Dr. _____ was one of your doctors? Is this correct?

YES	1	CONTINUE
NO	0	GO TO #21
DK	77	
REF	99	

15. Is Dr. _____ a....?

		YES	NO	DK	REF
a.	An urologist or surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
e1. OTHER SPECIFY: _____					

16. Where did you see Dr. _____?

Name of facility : _____

17. Our records indicate that Dr. _____ was one of your doctors? Is this correct?

YES	1	CONTINUE
NO	0	GO TO #24
DK	77	
REF	99	

18. Is Dr. _____ a....?

		YES	NO	DK	REF
a.	An urologist or surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
e1. OTHER SPECIFY: _____					

19. Where did you see Dr. _____?

Name of facility : _____

[CONTINUE TO #__]

20. [Besides Dr.(s) _____] Can you tell me [a/another] doctor with whom you discussed your prostate cancer diagnosis and treatment? (Can you spell their name?)

21. Is Dr. _____ a....[PHYSICIAN INDICATED ABOVE]?

		YES	NO	DK	REF
a.	An urologist or surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
e1. OTHER SPECIFY: _____					

22. Did you see Dr. _____ [PHYSICIAN ABOVE] at a...

			Name of Facility		Address
Clinic	1	Which clinic?	_____	Where is it located?	_____
Hospital	2	Which hospital?	_____	Where is it located?	_____
Private Practice Office	3	Which private practice?	_____	Where is it located?	_____
DK	77				
REF	99				

23. [Besides Dr.(s) _____] Can you tell me [a/another] doctor with whom you discussed your prostate cancer diagnosis and treatment? (Can you spell their name?)

24. Is Dr. _____ a....PHYSICIAN INDICATED ABOVE]?

		YES	NO	DK	REF
a.	An urologist/surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
	e1. OTHER SPECIFY: _____				

25. Did you see Dr. _____ [PHYSICIAN ABOVE] at a...

			Name of Facility		Address
Clinic	1	Which clinic?	_____	Where is it located?	_____
Hospital	2	Which hospital?	_____	Where is it located?	_____
Private Practice Office	3	Which private practice?	_____	Where is it located?	_____
DK	77				
REF	99				

[CONTINUE TO #33]

PATH B: IF THE PHYSICIAN IS NOT LISTED IN THE DATABASE

26. Can you tell me the name of a doctor with whom you discussed your prostate cancer diagnosis and treatment? (Can you spell their name?)

27. What kind of doctor is Dr. _____ [PHYSICIAN INDICATED ABOVE]?

		YES	NO	DK	REF
a.	An urologist/surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
e1. OTHER SPECIFY: _____					

28. Did you see Dr. _____ [PHYSICIAN ABOVE] at a...

			Name of Facility		Address
Clinic	1	Which clinic?	_____	Where is it located?	_____
Hospital	2	Which hospital?	_____	Where is it located?	_____
Private Practice Office	3	Which private practice?	_____	Where is it located?	_____
DK	77				
REF	99				

29. Can you remember another doctor with whom you discussed your prostate cancer diagnosis and treatment? (Can you spell their name?)

30. What kind of doctor is Dr. _____ [PHYSICIAN INDICATED ABOVE]?

		YES	NO	DK	REF
a.	An urologist/surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
e1. OTHER SPECIFY: _____					

31. Did you see Dr. _____ [PHYSICIAN ABOVE] at a...

			Name of Facility		Address
Clinic	1	Which clinic?	_____	Where is it located?	_____ _____
Hospital	2	Which hospital?	_____	Where is it located?	_____ _____
Private Practice Office	3	Which private practice?	_____	Where is it located?	_____ _____
DK	77				
REF	99				

[CONITNUE TO #33]

32. Which one of the following doctors would you say helped you the most with making decisions about your prostate cancer treatment? PROBE: REMIND THEM WHO THEY INDICATED ABOVE.

Dr. _____ [PHYSICIAN INDICATED ABOVE]	1	
Dr. _____ [OTHER PHYSICIAN INDICATED ABOVE]	2	
Dr. _____ [OTHER PHYSICIAN INDICATED ABOVE]	3	
OTHER	4	
33a. OTHER SPECIFY: _____		
DK	→	Which one of the following doctors would you refer to a friend or family member to?
REF	99	

KNOWLEDGE

Now we are going to talk a little bit about your experience with research studies both **before and after** your prostate cancer diagnosis.

33. First, before your prostate cancer diagnosis, did you ever participate in a research study about health?

YES	1	CONTINUE
NO	0	GO TO #
DK	77	
REF	99	

34. Can you tell me a little bit about the study? [PROBE: What were the researchers looking for?]

35. What did they ask you to do in this study?

		YES	NO	DK	REF
a.	Did they ask you to fill out a questionnaire or answer questions in an interview or focus group?	1	0	77	99
b.	Did they gather any blood or tissue samples from you for research purposes?	1	0	77	99
c.	Did they have you come in for special medical appointments, only for people participating in the study?	1	0	77	99
d.	Did they have you try a new medicine or treatment?	1	0	77	99
e.	Other	1	0	77	99
	e1. OTHER SPECIFY: _____				

36. Before your prostate cancer diagnosis, had you ever heard of the term **clinical trial**?

YES	1	IF YES →	As you know, a clinical trial is ...
NO	0	IF NO →	A clinical trial is a type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease (NCI). OR A clinical trial is a type of study that examines a new medicine, medical procedure, or treatment in order to prevent, diagnose or treat a medical condition.
DK	77		
REF	99		

37. Before your prostate cancer diagnosis, had you ever participated in a **clinical trial**?

YES	1	CONTINUE
NO	0	GO TO #41
DK	77	
REF	99	

38. What was being examined in this clinical trial?

		YES	NO	DK	REF
a.	A medicine? Like a pill, injection, or drug given through an IV.	1	0	77	99
b.	A procedure? Like a radiation treatment or type of surgery.	1	0	77	99
c.	Other?	1	0	77	99
	c1. OTHER SPECIFY: _____				

Now I am going to ask about research studies you may have participated in **since** your prostate cancer diagnosis.

39. Since your prostate cancer diagnosis, have you ever participated in a research study about health?

YES	1	CONTINUE
NO	0	GO TO #
DK	77	
REF	99	

40. Can you tell me a little bit about the study? What were the researchers looking for?

41. What did they ask you to do in this study?

		YES	NO	DK	REF
a.	Did they ask you to fill out a questionnaire or answer questions in an interview?	1	0	77	99
b.	Did they gather some blood, saliva, cells or other types of samples from you for research purposes?	1	0	77	99
c.	Did they have you come in for special medical appointments, only for people participating in the study?	1	0	77	99
d.	Did they have you try a new medicine or treatment?	1	0	77	99
e.	Other	1	0	77	99
	e1. OTHER SPECIFY: _____				

42. Since your prostate cancer diagnosis , have you ever participated in a **clinical trial**?

YES	1	CONTINUE
NO	0	GO TO #
DK	77	
REF	99	

43. What was being examined in this clinical trial?

		YES	NO	DK	REF
d.	A medicine? Like a pill, injection, or drug given through an IV.	1	0	77	99
e.	A procedure? Like a radiation treatment or type of surgery.	1	0	77	99
f.	Other?	1	0	77	99
	c1. OTHER SPECIFY: _____				

44. How important do you think it is for new drugs or treatments to be studied for their effects on people before they are used routinely by doctors?^{9, 10} Would you say...

Extremely Important	1
Very Important	2
Somewhat Important	3
Not Important	4
DK	77
REF	99

45. I am going to read a list of statements about clinical trials. Please indicate whether you think these statements are true, false, or you are unsure. ^{6,7}

	TRUE	FALSE	UNSURE	REF
KNOWLEDGE: RESEARCH ETHICS & CONSENT				
a. People who participate in clinical trials have the right to withdraw at any time. ⁷	1	2	3	99
b. Participation in a clinical trial is entirely voluntary. ⁷	1	2	3	99
c. Patients in clinical trials may have their medical information and names published. ⁷	1	2	3	99
d. A "Consent Form" is used to describe the important risks and potential benefits of entering a clinical trial. ⁷	1	2	3	99
e. Patients must sign a "Consent Form" when entering a clinical trial. ¹⁶	1	2	3	99
f. If a clinical trial is asking a very important question, doctors can force patients into a clinical trial. ⁸	1	2	3	99
g. Patients can be placed in a clinical trial without being told about it. ¹⁶	1	2	3	99
KNOWLEDGE: RANDOMIZATION				
h. The best way find out whether one treatment is better than another is to conduct a clinical trial where participants are assigned by chance to different treatments (random assignment). ³	1	2	3	99
i. The random assignment of treatment ensures that the group of patients receiving the different treatments in the study are as similar as possible. ¹	1	2	3	99
KNOWLEDGE: PURPOSE OF RESEARCH				
j. The purpose of clinical trials is to find out whether promising approaches to cancer are safe and effective (NCI).	1	2	3	99
k. All clinical trials are conducted by drug companies. ¹⁶	1	2	3	99

CLINICAL TRIAL BACKGROUND

46. Since your diagnosis with prostate cancer, have you ever **talked** with any of your doctors about clinical trials? ⁸

YES	1	CONTINUE
NO	0	GO TO # 54
DK	77	
REF	99	

47. Who brought it up; was it you or your doctor? ⁸

PARTICIPANT	1
DOCTOR	2
BOTH	3
DK	77
REF	99

48. Did you or your doctor talk about a specific trial?

YES	1
NO	0
DK	77
REF	99

49. Since your diagnosis, have you **been offered** the opportunity to participate in a clinical trial? ⁸

YES	1	CONTINUE	
NO	2	IF NO →	50. Why not? PROBE: WHY DID YOU NOT PARTICIPATE?
DK	77		
REF	99		

51. Since your diagnosis, what kind of doctors did you talk to about clinical trials?

		YES	NO	DK	REF
a.	An urologist or surgeon?	1	0	77	99
b.	A radiation oncologist?	1	0	77	99
c.	A medical oncologist?	1	0	77	99
d.	A primary care doctor?	1	0	77	99
e.	Other	1	0	77	99
e1. OTHER SPECIFY: _____					

52. Did you participate in the clinical trial?

YES	1	GO TO # 56	53. Why not? PROBE: WHY DID YOU NOT PARTICIPATE? _____ _____
NO	2	IF NO →	
DK	77		
REF	99		

54. [IF NO] Would you have wanted the opportunity to participate in a clinical trial?

YES	1	CONTINUE
NO	2	GO TO # 47
DK	77	
REF	99	

55. Do you think you would have participated?

say...	
Definitely	1
Probably	2
Maybe	3
Probably Not	4
No	5
DK	77
REF	99

56. If your prostate cancer were to get worse, would you want to participate in a clinical trial?

Would you say...?	
Definitely	1
Probably	2
Maybe	3
Probably Not	4
No	5
DK	77
REF	99

***IF PARTICPATED IN A CLINICAL TRIAL, **CONTINUE TO # 57**

IF NEVER PARTICIPATED IN A CLINICAL TRIAL, **SKIP TO # 71**

*****IF THE PATIENT PARTICIPATED IN A CLINICAL TRIAL**

57. How important were the following reasons as far as your decision to participate in the clinical trial?

	Would you say...?	Very Important	Important	Minor importance	Unimportant	DK	REF
a.	Having the opportunity to get the "new" drug therapy	1	2	3	4	77	99
b.	Know my prostate cancer would be watched more closely	1	2	3	4	77	99
c.	The wish to help future patients by helping to test "new" drugs/investigations	1	2	3	4	77	99
d.	You or someone you know had a positive experience in participating a in a former clinical trial	1	2	3	4	77	99

58. During the clinical trial, were there any questions you would have liked to ask, but did not ask?

Would you say...?	
Yes, many questions	1
Yes, a few questions	2
No, no questions	3
DK	77
REF	99

59. How satisfied were you with the information you were given about the clinical trial?

Extremely satisfied	1
Very satisfied	2
Somewhat satisfied	3
Not at all satisfied	4
DK	77
REF	99

60. How satisfied are you with the amount of time spent participating in the clinical trial?

Would you say...?	
Extremely satisfied	1
Very satisfied	2
Somewhat satisfied	3
Not at all satisfied	4
DK	77
REF	99

61. Overall, how satisfied were you with the clinical trial?

Would you say...?	
Extremely satisfied	1
Very satisfied	2
Somewhat satisfied	3
Not at all satisfied	4
DK	77
REF	99

62. Did your experiences during the trial change your general attitude towards clinical trials?

Would you say...?	
Yes, I view them more positively now	1
Yes, I view them more negatively now	2
No, I had no change in attitude	3
DK	77
REF	99

Now I am going to ask you a couple of questions about your attitudes towards future participation in a clinical trial.

63. Do you think you will participate in a clinical trial again?

Would you say...?	
Definitely	1
Probably	2
Maybe	3
Probably Not	4
No	5
DK	77
REF	99

64. If family members or close friends asked for your advice regarding participation in a clinical trial, would you advise them to participate?

Would you say...?	
Definitely	1
Probably	2
Maybe	3
Probably Not	4
No	5
DK	77
REF	99

ATTITUDES TOWARDS RESEARCH & PARTICIPATION

Now I am going to ask you some questions on your opinions about clinical trials.

65. I am going to read you a list of statements. For each one please let me know if you agree or disagree with the statement.

		Agree	Disagree	DK	REF
	ATTITUDES: PURPOSE OF RESEARCH				
a.	Clinical trials help us learn about the safety and effectiveness of new treatments. ¹⁶	1	2	77	99
	Clinical trials are important for the development of new cancer treatments. ⁴	1	2	77	99
b.	Clinical trials conducted by drug companies are as good as studies conducted by universities. ¹⁶	1	2	77	99
c.	Members of all racial/ethnic groups need to participate in clinical trials so that all groups can benefit from the results. ¹⁶	1	2	77	99
d.	I think all cancer patients should have the opportunity to take part in clinical trials. ⁴	1	2	77	99
e.	Clinical trials benefit researchers more than they benefit patients. ⁴	1	2	77	99
	Researchers are more interested in research as a way to advance their careers rather than finding new treatments. ²	1	2	77	99
	OTHER ATTITUDES				
f.	Patients in clinical trials get the latest cancer treatments. ⁴	1	2	77	99
	Patients in clinical trials are more closely watched regarding their cancer. ⁵	1	2	77	99
	Patients receive better care if they take part in a clinical trial. ⁴	1	2	77	99
g.	I would participate in a clinical trial if my doctor recommended it ⁴	1	2	77	99

ATTITUDES: REASONS NOT TO PARTICIPATE

The following statements are common reasons why people choose not to participate in clinical trials. Please let me know if you agree or disagree to the following statements.

		Agree	Disagree	DK	REF
a.	Patients often do not want to participate in a clinical trial because they do not want to their treatment to be chosen by chance. ⁴	1	2	77	99
	Patients often do not want to participate in a clinical trial because they want their doctor to choose their treatment. ⁴	1	2	77	99
b.	Patients often do not want to participate in a clinical trial because they are concerned that they might get a placebo or sugar pill rather than actual treatment. ⁴	1	2	77	99
c.	Participation in research is risky. ⁶	1	2	77	99
	Patients often do not want to participate in clinical trials because the risks outweigh the benefits. ⁷	1	2	77	99
d.	Patients often do not want to participate in clinical trials because they treat patients as guinea pigs. ⁴	1	2	77	99
e.	Clinical trials ask too much of patients such as extra lab tests, procedures, and more travel time. ⁴	1	2	77	99
f.	Patients are concerned that you need to be able to speak English to participate in a clinical trial. ⁷	1	2	77	99
g.	Patients don't understand much about clinical trials. ⁷	1	2	77	99
h.	Patients are concerned that may have to pay to participate in a clinical trial. ⁷	1	2	77	99
i.	Patients don't meet the eligibility or study entry criteria. ⁷	1	2	77	99
j.	Patients lack transportation. ⁷	1	2	77	99
k.	Patients are reluctant to complete paperwork. ⁷	1	2	77	99
l.	Patients are unable to take time from work, family, or other duties. ⁷	1	2	77	99
m.	Experimental treatments might make you sicker. ^(SG)	1	2	77	99

SOURCES OF INFORMATION

66. Have you ever tried to obtain information about clinical trials from any source?

YES	1	CONTINUE
NO	2	GO TO # 74
DK	77	
REF	99	

67. Please tell me which sources you used to find information on clinical trials?

	Did you use...	YES	NO	DK	REF
a.	the internet?	1	0	77	99
b.	a doctor?	1	0	77	99
c.	a nurse?	1	0	77	99
d.	brochures or pamphlets from the doctor's office?	1	0	77	99
e.	friends and/or family?	1	0	77	99
f.	someone with cancer?	1	0	77	99
g.	cancer organization, like the American Cancer Society or the National Cancer Institute?	1	0	77	99
h.	a telephone health information line?	1	0	77	99
i.	any other source?	1	0	77	99
	i1. SPECIFY: _____				

68. The next time you have a strong need to get information about clinical trials, where will you go first?

	Will you use...	YES	NO	DK	REF
a.	the internet?	1	0	77	99
b.	a doctor?	1	0	77	99
c.	a nurse?	1	0	77	99
d.	brochures or pamphlets from the doctor's office?	1	0	77	99
e.	friends and/or family?	1	0	77	99
f.	someone with cancer?	1	0	77	99
g.	cancer organization, like the American Cancer Society or the National Cancer Institute?	1	0	77	99
h.	a telephone health information line?	1	0	77	99
i.	any other source?	1	0	77	99
	i1. SPECIFY: _____				

SOCIODEMOGRAPHICS

[IF LEP]

69. In general, in what language do you prefer to receive your medical care? ¹

ENGLISH	1
SPANISH	2
CANTONESE	3
TAGALOG	4
BOTH EQUALLY – ENGLISH/SPANISH	5
BOTH EQUALLY – ENGLISH/CANTONESE	6
BOTH EQUALLY – ENGLISH/TAGALOG	7
OTHER	8
48a. OTHER SPECIFY: _____	

70. In general, do you prefer to have someone interpret for you when you speak with a doctor? [An interpreter could be a family member or friend, hospital staff, or a professional provided by the hospital specifically to interpret for you.] ¹

YES	1	
NO	0	
DK	77	
REF	99	

71. [LANGUAGE ACCULTURATION] '___' = OTHER LANGUAGE INDICATED IN QUESTION 6

	Would you say...?	Only —	— better than English	Both equally well	English better than —	Only English	DK	REF
a.	In general, what language do you read and speak? ¹⁴	1	2	3	4	5	77	99
b.	What language do you usually speak at home? ¹⁴	1	2	3	4	5	77	99
c.	In which language do you usually think? ¹⁴	1	2	3	4	5	77	99
d.	What language do you usually speak with your friends? ¹⁴	1	2	3	4	5	77	99

72. [HEALTH LITERACY]

		Always	Often	Sometimes	Rarely	Never	DK	REF
a.	How often do you have problems learning about your medical condition because of difficulty understanding written information?	1	2	4	5	6	77	99
b.	How often are you confident (comfortable) with filling out medical forms by yourself?	1	2	4	5	6	77	99
c.	How often do you have someone help you read hospital materials?	1	2	4	5	6	77	99

73. In what country were you born?

U.S.	1		
OTHER COUNTRY:	2	→	74. In total, how many years have you lived in the U.S.?
DK	77		77
REF	99		99

75. Are you...?

Married	1
Never married	2
With a long-term partner	3
Legally separated or divorced	4
Widowed	5
OTHER	6
54a. OTHER SPECIFY: _____	
DK	77
REF	99

76. What is the highest year of school you have completed?

GRADE SCHOOL		COLLEGE/UNIVERSITY/COMMUNITY COLLEGE	
1 ST GRADE	1	1 ST YEAR (FRESHMAN)	13
2 ND GRADE	2	2 ND YEAR (SOPHOMORE) (AA)	14
3 RD GRADE	3	3 RD YEAR (JUNIOR)	15
4 TH GRADE	4	4 TH YEAR (SENIOR) (BA/BS)	16
5 TH GRADE	5	GRADUATE OR PROFESSIONAL SCHOOL	18
6 TH GRADE	6	DK	77
7 TH GRADE	7	REF	99
8 TH GRADE	8		
HIGH SCHOOL OR EQUIVALENT			
9 TH GRADE	9		
10 TH GRADE	10		
11 TH GRADE	11		
12 TH GRADE	12		

77. Are you...?

Working full time	1
Working part time	2
A homemaker	3
Retired	4
A student	5
Unemployed	6
OTHER	7
56a. OTHER SPECIFY: _____	
DK	77
REF	99

78. How many people live in your household, including yourself? (By "household", I mean people who live together and depend on the same incomes.)

	PEOPLE	
	DK	77
	REF	99

79. During the past year, what was your household's total annual income before taxes? I'll be reading you some categories to choose from. Again, this information is completely confidential. Would it be easiest for you if I read the categories per year, per month, or per week?

PER YEAR	PER MONTH	PER WEEK	
\$5000 or less	\$417 or less	\$97 or less	1
\$5001 to \$10,000	\$418 to \$833	\$98 to \$192	2
\$10,001 to \$20,000	\$834 to \$1,666	\$193 to \$384	3
\$20,001 to \$40,000	\$1,667 to \$3,333	\$385 to \$769	4
\$40,001 to \$70,000	\$3,334 to \$5,833	\$770 to \$1,346	5
More than \$70,000	More than \$5,833	More than \$1,346	6
			DK 77
			REF 99

This is the end of the survey. Before we hang up I'd like to verify with you the address of the best place for me to mail your \$10 gift card as a thank you for participating.

NAME:	
STREET1:	
STREET2:	
CITY & ZIP	

I also would like to know whether you might be willing to participate in future health studies. Saying "YES" does not commit you to anything; it just means we might send you information about future studies.

YES	1
NO	0
DK	77
REF	99

Thank you again for your time and participation. It is greatly appreciated.

The Inclusion of Minority Patients in Prostate Cancer Clinical Trials

Thank you for taking time to complete this short survey about the referral of ethnic minorities into prostate cancer clinical trials. Your answers will be kept completely confidential. Your individual privacy will be maintained in all published and written data resulting from the study. Your participation in the survey is voluntary.

It should take less than 10 minutes to answer all of the questions.

To learn more about this study, visit: <http://dgim.ucsf.edu/prostate/physiciansurvey.html>.

If you have any questions regarding the study or would like to speak to Dr. Celia Kaplan, Principal Investigator, please contact her by e-mail at celia.kaplan@ucsf.edu or by phone at (415) 502-5601.

Section A. Your work-related time and specialty

1. On average, what percentage of your work-related time each week do you spend in...

a.	Patient care (<i>e.g., seeing patients, calling consultants, reviewing lab results</i>)	_____ %
b.	Teaching activities	_____ %
c.	Research activities	_____ %
d.	Administrative activities (<i>committee & other professionally-related activities</i>)	_____ %

Total should add to 100%

2. What is your primary medical specialty? *Please check one answer only.*

Urology	☐ 1	
Radiation Oncology	☐ 2	
Hematology/ Oncology	☐ 3	
Primary Care	☐ 4	
Internal Medicine	☐ 5	
Primary Care	☐ 6	→ <i>Please specify:</i> _____

3. On average, how many prostate cancer patients (newly diagnosed or undergoing treatment) do you personally see treat at your primary practice site per month?

_____ prostate cancer patients per month

4. What proportion of your practice is made up of prostate cancer patients?

All	Almost All	Some	Almost None	None
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. Are prostate cancer clinical trials conducted at your site?

Yes	☐ 1		
No	☐ 0 → 15. How far away is the nearest clinical trial site for prostate cancer clinical trials?	a.	Less than 15 minute drive ☐ 1
		b.	15-30 minute drive ☐ 2
		c.	30-60 minute drive ☐ 3
		d.	Over 1 hour drive ☐ 4
		e.	Other language(s) ☐ 5
		↳ Please specify: _____	

Section B. Demographics characteristics about yourself

6. In what year did you graduate from medical school? _____

7. What is your gender? Female ☐ 1 Male ☐ 2

8. In which country did you graduate from medical school? Please check one answer only.

United States ☐ 1	Another country ☐ 2	→ Please specify: _____
--	--	-------------------------

9. In what year were you born? _____

10. Are you Latino/a or Hispanic?

Yes	☐ 1
No	☐ 0

11. What is your race/ethnicity? Please check one answer only.

Black or African American	☐ 1
Asian, Asian American or Pacific Islander	☐ 2
White, European American or Caucasian	☐ 3
American Indian or Alaska Native	☐ 4
Other	☐ 5 → Please specify: _____

Section C. Characteristics of your primary practice site, patients, and staff

12. Which one of the following best describes your primary practice site? Please check one answer only.

Private Practice (Solo, single-specialty group, or multi-specialty group)	☐ 1
Group-model HMO (e.g., Kaiser Permanente)	☐ 2
Public/community health center	☐ 3
Public hospital	☐ 4
VA hospital/clinic	☐ 5
University/medical school-based practice (not including public or VA hospitals)	☐ 6
Hospital (Community, Non-profit, For-Profit)	☐ 7
Other setting please specify	☐ 8

13. Using your best estimate, what percentage of your patients is insured by...

a.	Medicare (including supplemental insurance)	_____ %
b.	Medicaid	_____ %
c.	Private insurance or HMO (including Kaiser)	_____ %
d.	No insurance/free care/self-pay	_____ %

14. Using your best estimate, what percentage of your patients is...

a.	Black or African American	_____ %
b.	Asian, Asian American or Pacific Islander	_____ %
c.	Latino/a or Hispanic	_____ %
d.	White, European American, or Caucasian	_____ %
e.	Other	_____ %

15. Using your best estimate, what percentage of your patients *requires* interpretation of a language other than English to receive health care services? Write "0" if all of your patients speak English.

_____ %

16. Other than English, do you speak any of the following languages with your patients?

a.	Spanish	☐	
b.	Chinese (Cantonese or Mandarin)	☐	
c.	Tagalog	☐	
d.	Vietnamese	☐	
e.	Korean	☐	
f.	Russian	☐	
g.	Other language	☐	→ Please specify: _____

17. Do any of your patients speak any of the following languages as their primary language?

a.	Spanish	☐	
b.	Chinese (Cantonese or Mandarin)	☐	
c.	Tagalog	☐	
d.	Vietnamese	☐	
e.	Korean	☐	
f.	Russian	☐	
g.	Other language	☐	→ Please specify: _____

18. Are any of the following language interpreter services available at your primary practice site?

		YES	NO
a.	Interpretation by bilingual staff, including yourself (<i>NOT a professional interpreter</i>)	☐ _1	☐ _0
b.	Volunteer onsite interpreters (<i>NOT staff</i>)	☐ _1	☐ _0
c.	Professional onsite interpreters	☐ _1	☐ _0
d.	Professional interpreter services by telephone or video	☐ _1	☐ _0

19. Does your primary practice site have a bilingual (English and any other language) staff person (including yourself) in any of the following positions?

	YES	NO	No staff in this position
a. Receptionist, front desk or appointment desk	☐ 1	☐ 0	☐ 99
b. Nurse, nursing assistant, medical assistant	☐ 1	☐ 0	☐ 99
c. Physician, physician's assistant or nurse practitioner	☐ 1	☐ 0	☐ 99
d. Laboratory assistant	☐ 1	☐ 0	☐ 99
e. Other staff _____ Please specify	☐ 1	☐ 0	☐ 99

20. If you answered "Yes" to any of the above in Question 18: Which of the following languages does your staff person(s) speak? Please skip to Question 19 if you did not answer "Yes".

	YES	NO	
a. Spanish	☐ 1	☐ 0	
b. Chinese (Cantonese or Mandarin)	☐ 1	☐ 0	
c. Tagalog	☐ 1	☐ 0	
d. Vietnamese	☐ 1	☐ 0	
e. Korean	☐ 1	☐ 0	
f. Russian	☐ 1	☐ 0	
g. Other language(s)	☐ 1	☐ 0	→ Please specify: _____

Section D. Clinical trial referral and recruitment

21. In the past two years, how many prostate cancer clinical trials have you been involved in as a principal investigator or co-investigator? If none, please enter "0".
_____ prostate cancer clinical trials

22. With respect to prostate cancer clinical trials, in the past year have you...

	YES	NO
a. ...had patients inquire about prostate cancer clinical trials?	☐ 1	☐ 0
b. ...referred or recruited patients to prostate cancer clinical trials administered by others?	☐ 1	☐ 0
c. ...recruited patients for a prostate cancer clinical trial for which you were principal investigator or co-investigator?	☐ 1	☐ 0

23. In the past year, have you referred or recruited patients to prostate cancer clinical trials sponsored by the...

	YES	NO
a. National Cancer Institute (NCI)	☐ 1	☐ 0
b. NCI Clinical Trial Cooperative Groups (e.g., ECOG, NSABP)	☐ 1	☐ 0
c. Pharmaceutical/Industry	☐ 1	☐ 0
d. I have referred or recruited but do not know who sponsored the study	☐ 1	☐ 0

24. How often in the past year have you done the following *with your prostate cancer patients*?

		YES	NO
a.	Discussed the possibility of their enrollment in prostate cancer clinical trials	☐ ₁	☐ ₀
b.	Given them informational resources (e.g., brochures, internet referrals) about prostate cancer clinical trials	☐ ₁	☐ ₀
c.	Discussed with them the potential benefits and risks/burdens of a specific prostate cancer clinical trial	☐ ₁	☐ ₀
d.	Referred them to a specific prostate cancer clinical trial.	☐ ₁	☐ ₀
e.	Enrolled them in a specific prostate cancer clinical trial.	☐ ₁	☐ ₀

25. In the past year, have you referred or recruited patients to any of the following types of prostate cancer clinical trials?
Please check all that apply.

a.	Adjuvant or neoadjuvant therapy	☐
b.	Surgical	☐
c.	Radiation	☐
d.	Chemotherapy	☐
e.	Biological therapy or immunotherapy	☐
f.	Hormonal therapy	☐
g.	Stem cell or bone marrow	☐
h.	Supportive care (e.g., treating clinical trial side effects)	☐
i.	Prevention trials	☐
j.	Other types of trials	☐ → Please specify: _____

26. Using your best estimate, how many patients have you enrolled or referred to prostate cancer clinical trials *in the past year*? Write "0" if you did not enroll or refer any patients.
_____ Patients

27. In your experience, who typically initiates a discussion about prostate cancer clinical trials? Please check one answer only.

My patients initiate the discussion	☐ ₁
I initiate the discussion	☐ ₂
My patients and I both initiate the discussion	☐ ₃
I do not discuss clinical trials with my patients	☐ ₄

28. In general, to what degree is each of these factors a **barrier for you** in referring or recruiting a prostate cancer patient to a clinical trial?

		Major Barrier	Moderate Barrier	Minor Barrier	Not a Barrier
a.	Eligibility or study entry criteria of cancer clinical trials.	☐ ₁	☐ ₂	☐ ₃	☐ ₄
b.	My concern about inadequate reimbursement from research sponsors	☐ ₁	☐ ₂	☐ ₃	☐ ₄
c.	My concern that trial treatment will be inferior to standard treatments	☐ ₁	☐ ₂	☐ ₃	☐ ₄
d.	My concern that patients referred to trials will not return to my practice	☐ ₁	☐ ₂	☐ ₃	☐ ₄
e.	Time and effort required to explain trials to a patient	☐ ₁	☐ ₂	☐ ₃	☐ ₄
f.	A lack of time dedicated for research	☐ ₁	☐ ₂	☐ ₃	☐ ₄
g.	My concern that trials cannot accommodate non-English speakers	☐ ₁	☐ ₂	☐ ₃	☐ ₄
h.	My concern that the risks of current trials outweigh the benefits	☐ ₁	☐ ₂	☐ ₃	☐ ₄
i.	Most of the trials I have seen offer little or no benefit over standard treatment	☐ ₁	☐ ₂	☐ ₃	☐ ₄
j.	A lack of information about trials	☐ ₁	☐ ₂	☐ ₃	☐ ₄
k.	Patient's lack of adequate insurance coverage	☐ ₁	☐ ₂	☐ ₃	☐ ₄
l.	Patient's lack of understanding of what clinical trials are	☐ ₁	☐ ₂	☐ ₃	☐ ₄
m.	Patient's lack of transportation	☐ ₁	☐ ₂	☐ ₃	☐ ₄
n.	Patient's possible non-adherence with the study protocol	☐ ₁	☐ ₂	☐ ₃	☐ ₄
o.	Patient's reluctance to complete paperwork	☐ ₁	☐ ₂	☐ ₃	☐ ₄
p.	Patient's inability to take time to participate	☐ ₁	☐ ₂	☐ ₃	☐ ₄

29. In general, to what degree would the following factors serve as an **incentive for you** to refer or recruit a prostate cancer patient to a clinical trial?

		Major Barrier	Moderate Barrier	Minor Barrier	Not a Barrier
a.	The clinical trial is likely to improve the patient's medical condition	☐ ₁	☐ ₂	☐ ₃	☐ ₄
b.	Patient's lack of other means to pay for health care	☐ ₁	☐ ₂	☐ ₃	☐ ₄
c.	Patient's desire to take advantage of the latest available treatment options	☐ ₁	☐ ₂	☐ ₃	☐ ₄
d.	Lack of other effective treatment options	☐ ₁	☐ ₂	☐ ₃	☐ ₄
e.	Prevention of a recurrence or second cancer	☐ ₁	☐ ₂	☐ ₃	☐ ₄
f.	Patient would have access to a drug that is difficult to get authorization for outside of a clinical trial	☐ ₁	☐ ₂	☐ ₃	☐ ₄
g.	Contact with academic researchers				

You have completed our survey.
 Thank you for your time and assistance!
 Please return this questionnaire in the envelope provided.