

UCSF COMMITTEE ON HUMAN RESEARCH
EXPEDITED REVIEW APPLICATION

Please date form: ___

Is this a NIH “Just in Time”
 submission? Yes No

If also applying to the **Clinical and Translational Science Institute (CTSI) at UCSF**, please submit one copy of this application to the CTSI Clinical Research Center where your study will take place. Visit <http://ctsi.ucsf.edu/index.html>, <http://gcrsfgh.ucsf.edu/>, or <http://www.gcrc.ucsf.edu/> for additional instructions regarding the CTSI application process.

[General Instructions](#) | [Submission Checklist](#) | [Frequently Asked Questions](#)

Street Address:
 Committee on Human Research (CHR)
 Office of Research
 3333 California Street, Suite 315
 University of California
 San Francisco, CA 94118

Campus Mailbox:
 CHR
 Box 0962

Office Contact for questions:
 Office: (415) 476-1814
 Facsimile: (415) 502-1347
 e-mail: chr@ucsf.edu

PART 1: ADMINISTRATIVE REQUIREMENTS

- [Eligibility requirements for Principal Investigator, Co-Principal Investigator and Contact Person](#)
- [Training requirements](#)

A. Principal Investigator:		
Name and degree	University Title	Department
Campus Mailing Address (Box No.)	Phone Number	E-mail Address
Co-Principal Investigator:		
Name and degree	University Title	Department
Campus Mailing Address (Box No.)	Phone Number	E-mail Address
Additional Contact Person (if any):		
Name	University Title	Department
Campus Mailing Address (Box No.)	Phone Number	E-mail Address
Send correspondence to (check <i>one</i>):	<input type="checkbox"/> PI only <input type="checkbox"/> PI and Co-PI <input type="checkbox"/> PI and Additional Contact Person	
Study Title:	Application Type:	
	<input type="checkbox"/> New Expedited Committee Application <input type="checkbox"/> Expedited Review Category : <input type="checkbox"/> Response to “Contingent” or “Return” letter <input type="checkbox"/> Modification <input type="checkbox"/> Renewal Current CHR #: ___ Expiration date: ___	
UCSF Sites (Check all that apply):		
<input type="checkbox"/> UCSF <input type="checkbox"/> Cancer Center <input type="checkbox"/> Mt. Zion <input type="checkbox"/> SFGH <input type="checkbox"/> ITN <input type="checkbox"/> Fresno		
CTSI CRC Sites (Check all that apply):		

<input type="checkbox"/> Moffitt Inpatient Unit	<input type="checkbox"/> SFGH Inpatient Unit	<input type="checkbox"/> Moffitt Pediatric Inpatient Unit	<input type="checkbox"/> Kaiser Oakland DOR
<input type="checkbox"/> Moffitt Outpatient Unit	<input type="checkbox"/> SFGH Outpatient Unit	<input type="checkbox"/> Moffitt Pediatric Outpatient Unit	<input type="checkbox"/> CHORI Pediatric
<input type="checkbox"/> Mt. Zion Outpatient unit	<input type="checkbox"/> VAMC Outpatient Unit	<input type="checkbox"/> Pediatric Clinical Care Units	<input type="checkbox"/> CHORI Adult
<input type="checkbox"/> Tenderloin Medical Center			
UCSF Affiliated Sites (Check all that apply):			
<input type="checkbox"/> VAMC	<input type="checkbox"/> Gladstone	<input type="checkbox"/> Gallo	<input type="checkbox"/> SFDPH
<input type="checkbox"/> IOA	<input type="checkbox"/> BSRI	<input type="checkbox"/> BCP	
UC Campus – Read the guidance to rely on another UC Campus IRB and submit the correct Notice of Intent to Rely form.			
<input type="checkbox"/> UC Berkeley	<input type="checkbox"/> UC Irvine	<input type="checkbox"/> UC Riverside	<input type="checkbox"/> UC Santa Cruz
<input type="checkbox"/> UC Davis	<input type="checkbox"/> UC Los Angeles	<input type="checkbox"/> UC San Diego	
<input type="checkbox"/> Lawrence Berkeley National Laboratory	<input type="checkbox"/> UC Merced	<input type="checkbox"/> UC Santa Barbara	
Non-UCSF Affiliated Sites - Attach IRB Approval Certification Supplement for all sites checked below:			
<input type="checkbox"/> Foreign Country <input type="checkbox"/> Other Institution: _____			
<input type="checkbox"/> Other Community-Based Site: _____			

B. Funding: If this study is eligible for “Just in Time” NIH review, do not submit your application to the CHR until you have received notification from the federal granting agency that your study appears to be in a fundable range. If this study is federally funded please complete section B.6.
Check all that apply:

1. Type of funding:	2. Source of funding:	3. Funds will be awarded to/through:
<input type="checkbox"/> Contract/Grant	<input type="checkbox"/> Federal Government	Dept./ORU:
<input type="checkbox"/> Subcontract	<input type="checkbox"/> Other Gov. (e.g., State, local)	<i>Institution</i> <i>Federal Wide Assurance (FWA) No.</i>
<input type="checkbox"/> Drug/device donation	<input type="checkbox"/> Industry**	<input type="checkbox"/> UCSF 00000068
<input type="checkbox"/> Departmental	<input type="checkbox"/> Other Private	<input type="checkbox"/> Blood Centers of the Pacific 00002111
<input type="checkbox"/> Gift	<input type="checkbox"/> Campus/UC-Wide program	<input type="checkbox"/> Blood Systems Research Institute 00006454
<input type="checkbox"/> Student project	<input type="checkbox"/> Departmental Funds	<input type="checkbox"/> Gallo Institute 00000304
<input type="checkbox"/> Other: ___	<input type="checkbox"/> Other:	<input type="checkbox"/> Gladstone Institute 00000087
Have funds been awarded?	Specify name of source designated above: ___	<input type="checkbox"/> Institute on Aging 00002525
<input type="checkbox"/> Yes <input type="checkbox"/> Pending <input type="checkbox"/> No		<input type="checkbox"/> NCIRE 00000256
Award No.: ___		<input type="checkbox"/> S.F. Dept. of Public Health 00000162
Proposal Express number(s): ___		<input type="checkbox"/> SFVAMC Research Office 00000280

4. UCSF (or affiliate) financial contact person for IRB review recharge:

5. Grant Title and PI (if different from above):

6. CHR Protocol/Federal Grant or Contract Comparison (New CHR Studies Only)
If this study is federally funded, please submit one copy of one of the following documents (unless there is more than one grant or contract involved; in that case, submit one copy for each associated grant or contract). Please indicate which document you have attached:

- The Research Plan, including the Human Subjects, Section E of your NIH grant
- For other federal proposals (contracts or grants), the section of the proposal describing human subjects work, or
- The section of your progress report if it provides the most current information about your human subjects work.

7. If there are any significant discrepancies between this CHR application and the grant or contract or if this is a training grant please explain here:

8. Secondary sponsors: If there are multiple sources of funding for this study, please describe the additional funding:

C. [Scientific or Scholarly Review](#):

Is this an investigator-initiated study? Yes No

This study has received scientific or scholarly review from (check all that apply):
The results of this review must be communicated to the CHR as part of the CHR review process.

- NIH* Cancer Center** JTSI CRC SFVAMC CHORI Kaiser Oakland DOR GESCR

objectives.

- I assure that the protected health information I obtain, if any, as part of this research will not be reused or disclosed to any parties other than those described in the CHR-approved protocol, except as required by law.
- I assure that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place *before* implementing the research project, and that the research will *stop* if adequate resources become unavailable.

Principal Investigator's Signature

Date

PART 2: STUDY DESIGN

Complete items A-E using clear, concise, non-technical, lay language (i.e., the type of language used in a newspaper article for the general public) wherever possible. Define all acronyms. Use caution when cutting and pasting from another application or protocol to ensure that information is complete, supplemented where necessary, is pasted in a logical order, and is relevant to the specific section.

Space limits are recommendations and should be adjusted as needed, but the total length for sections A-E should not exceed 5 pages.

For modifications and renewals, please highlight in *italics* all changes from previously approved version.

A. Synopsis (Briefly summarize the study.)

Space limit: quarter page

B. Hypothesis(es): Briefly explain the hypothesis(es) to be tested. If the study is not designed to test a hypothesis, simply state "None."

C. Specific Aims: List the specific aims.

D. Background and Significance: Briefly sketch the scientific background leading to the present proposal, critically evaluate existing knowledge (with references), and specifically identify the gaps the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives.

E. Preliminary Studies: Preliminary data often aid reviewers in assessing how valuable the project is likely to be. If graphs or tables are used to convey information, please maintain a consistent style and make sure that fonts are no less than 11-point in size. If no preliminary data are available, it may be helpful to briefly indicate why this proposed study is a reasonable starting point.

F. Design

1. (Check all that apply):

<input type="checkbox"/> Randomized <input type="checkbox"/> Blinded <input type="checkbox"/> Investigational intervention without random assignment <input type="checkbox"/> Behavioral	
If this study has any of the formal designations below, please indicate: <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Open Label Extension: If so, specify CHR Approval Number for original study: ___	
<input type="checkbox"/> Multicenter: If so, is the UCSF PI the lead investigator, coordinating center or the prime grant holder? If yes, please address how the following information will be recorded and shared among sites:	<input type="checkbox"/> Yes <input type="checkbox"/> No
a. How will safety updates, interim results, or other information that may impact risks to the subject or others be communicated among sites?	
b. How will any modification(s) to the protocol or consent document(s) be shared among sites?	
Note: It is also the responsibility of the coordinating center and/or prime grant holder to maintain the IRB Approvals for all study sites.	
2. Community Engagement – The following questions are designed to gather information about the extent to which UCSF researchers are seeking to create or have created ongoing clinical and translational research partnerships with community members. <i>A community-based clinical and translational research partnership is defined as a research partnership that actively engages community participants in aspects of the research that extend beyond volunteering to be a subject in a clinical trial.</i>	
a. Community-Based Research: Does this project involve the development or continuation of community-based research partnerships between UCSF and local members of community-based advocacy groups; religious, ethnic, or neighborhood organizations; schools; local government agencies; local businesses; or other local organizations?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Practice-Based Research: Does this project involve the development or continuation of research partnerships between UCSF and local community-based clinicians (such as dentists, nurses, pharmacists, physicians, or other health professionals), organizations that provide healthcare (such as local clinics, medical groups, pharmacies, or insurance providers), or other health-care organizations (such as professional membership societies)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Note: if other sites are engaged in the research they must be listed in Part 1 under Non-UCSF Affiliated Sites	
3. Additional description of general study design. Attach flow diagram if appropriate. Space limit: half page	

<p>G. Statistical Analysis: Briefly describe what statistical analysis(es) of which outcome will be applied in order to address each primary aim. Examples of statistical analyses include:</p> <ul style="list-style-type: none"> <i>Calculation of descriptive statistics such as mean, median, SD, range, tallies.</i> <i>Examination of graphs such as outcome vs. time, scatterplots of two variables, Kaplan-Meier curves.</i> <i>Estimation of differences between two groups with comparison by t-test or Mann-Whitney test.</i> <i>Estimation and testing of within-person changes by matched t-test or Wilcoxon signed-rank test.</i> <i>Multiple linear regression, logistic regression, or Cox proportional hazards regression.</i> <i>Repeated measures models (usually requires the help of a statistician).</i> <p>For qualitative research, briefly describe how qualitative data will be analyzed.</p>
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<p>H. Sample Size: Indicate how many subjects will be studied and why this number was chosen.</p>
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PART 3: PROCEDURES

A. Check all that apply.
<input type="checkbox"/> Human Biological Specimen Banking Attach - Banking Supplement
<input type="checkbox"/> Genetic Testing

B. Please list, in sequence, all study procedures, tests, and treatments required for the study. Indicate which would be done even if a subject does not enroll in the study. Include a detailed explanation of any experimental procedures. Attach table if available.

C. Time Commitment: Indicate how much time will be required of the subjects, per visit and in total for the study.

D. Facilities: List the clinics and/or other specific locations where study procedures will be performed. Please provide a description of the facility if appropriate. For example, if study procedures involving more than minimal risk take place in a research facility, a description of the equipment on hand needed to protect participants would be appropriate. Attach letters of support indicating knowledge and endorsement of this study from any involved units or name investigators from those units under Key Personnel.

E. Will any interviews, questionnaires, surveys or focus groups be conducted for the study? If “Yes,” please name any standard instruments used for this study and attach any non-standard instruments.	<input type="checkbox"/> Yes <input type="checkbox"/> No

F. Will any procedures or tests be done off-site by non-UCSF personnel? If “Yes,” please explain.	<input type="checkbox"/> Yes <input type="checkbox"/> No

PART 4: ALTERNATIVES

A. Describe the alternatives to study participation that are available to prospective subjects.

B. Is study drug or treatment available off-study? If “Yes,” discuss this in the consent form.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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PART 5: RISKS AND BENEFITS

A. Risks and Discomforts:

1. Describe the risks and discomforts of any study procedures.

2. Describe the steps you have taken to minimize the risks/discomforts to subjects: Examples include: designing the study to make use of procedures involving less risk when appropriate; minimizing study procedures by taking advantage of clinical procedures conducted on the study participants; mitigating risks by planning special monitoring or conducting supportive interventions for the study. If appropriate, provide a rationale for risky procedures.

B. Confidentiality and Privacy: Privacy concerns people, whereas confidentiality concerns data. Specifically, confidentiality refers to the researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed and disseminated. While privacy refers to a person’s desire to control the access of others to themselves. **Address each of the following privacy issues in questions 1-3 below:**

1. How will the investigator access information from or about participants?

2. How will the investigator maintain privacy in the research setting(s),

3. What are the consequences to participants of a loss of privacy (e.g., risks to reputation, insurability, other social risks):

The following questions address confidentiality issues:

4. Identifiers: Please indicate all identifiers that may be included in the research records for the study. Check all that apply.

- | | | |
|--|--|--|
| <input type="checkbox"/> Names | <input type="checkbox"/> Social Security Numbers* | <input type="checkbox"/> Device identifiers/Serial numbers |
| <input type="checkbox"/> Dates | <input type="checkbox"/> Medical record numbers | <input type="checkbox"/> Web URLs |
| <input type="checkbox"/> Postal address | <input type="checkbox"/> Health plan numbers | <input type="checkbox"/> IP address numbers |
| <input type="checkbox"/> Phone numbers | <input type="checkbox"/> Account numbers | <input type="checkbox"/> Biometric identifiers |
| <input type="checkbox"/> Fax numbers | <input type="checkbox"/> License/Certificate numbers | <input type="checkbox"/> Photos and comparable images |
| <input type="checkbox"/> Email address | <input type="checkbox"/> Vehicle id numbers | <input type="checkbox"/> Any other unique identifier |
| <input type="checkbox"/> None of the 18 identifiers listed above | | *Required for studies conducted at the VA |

5. Determining Whether HIPAA Regulations Apply to This Study: Please answer the questions below for the items identified in the above section. Check all that apply:

Is any of the study data: <input type="checkbox"/> Derived from a medical record? <i>Please identify source:</i> <input type="checkbox"/> Added to the hospital or clinical medical record? <input type="checkbox"/> Created or collected as part of health care? <input type="checkbox"/> Used to make health care decisions?	HIPAA regulations apply. The information identified in section B.4. above is PHI.
<input type="checkbox"/> Obtained from the subject, including interviews, questionnaires? <input type="checkbox"/> Obtained from a foreign country or countries only? <input type="checkbox"/> Obtained from records open to the public? <input type="checkbox"/> Obtained from existing research records? <input type="checkbox"/> None of the above.	HIPAA regulations do not apply. The information identified in section B.4. above is not PHI.

If HIPAA regulations apply, you are required to obtain individual [subject authorization](#) or a [CHR-approved waiver of authorization](#), or both, to be allowed access to medical records. For the VA, use the [SFVAMC authorization](#). (The one exception to these requirements is the use of a [Limited Data Set](#) along with a [Data Use Agreement](#).)

6. Use and Disclosure of Personal Health Information: Please indicate to whom or where you may disclose any of the identifiers listed above as part of the study process. Check all that apply:

We do not plan to share any of the personally identifying information listed above outside the research team.

The subject’s medical record

<input type="checkbox"/> The study sponsor: <i>please indicate</i> : <input type="checkbox"/> The US Food & Drug Administration (FDA) <input type="checkbox"/> Others: <i>please indicate</i> : <input type="checkbox"/> A Foreign Country or Countries
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7. Data Security: Identifiable data should not be stored on laptops, PDA's or other portable devices. Please indicate how study data are kept secure. Check all that apply:

<input type="checkbox"/> Data are coded; data key is destroyed at end of study or <i>provide date</i> : <input type="checkbox"/> Data are coded; data key is kept separately and securely <input type="checkbox"/> Data are kept in locked file cabinet <input type="checkbox"/> Data are kept in locked office or suite	<input type="checkbox"/> Electronic data are protected with a password <input type="checkbox"/> Data are stored on a secure network
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8. Describe any additional steps taken to assure that identities of subjects and any of their health information which is protected under the law is kept confidential. If video or audio tapes will be made as part of the study, [disposition of these tapes](#) should be addressed.

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9. Reportable Information: Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse) or ethically requires action (e.g., suicidal ideation)? If "Yes," please explain below and include a discussion of the reporting requirements in the consent form.	<input type="checkbox"/> Yes <input type="checkbox"/> No
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C. Benefits: 1. Are there potential direct benefits to study subjects? If "Yes," please describe below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
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2. What are the potential benefits to society?

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D. Risk/Benefit Analysis: How do the benefits of the study outweigh the risks to subjects?

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PART 6: SUBJECT INFORMATION

A. Number of Subjects: 1. How many subjects will be enrolled at UCSF and affiliated institutions? 2. How many subjects will be enrolled at all sites (i.e., if multicenter study)? 3. How many people do you estimate you will need to consent and screen here (but not necessarily enroll) to get the needed subjects?	
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B. Types of Subjects: Check all that apply. Click on links for additional instructions.

<input type="checkbox"/>	Minors Attach - Inclusion of Minors Supplement
<input type="checkbox"/>	Subjects unable to consent Attach - Surrogate Consent or Emergency Waiver of Consent Supplement
<input type="checkbox"/>	Subjects with Diminished Capacity to Consent
<input type="checkbox"/>	Subjects Unable to Read, Speak, or Understand English – Complete Part 8.D of this application
<input type="checkbox"/>	Pregnant Women – Complete Part 6.G of this application
<input type="checkbox"/>	Fetuses
<input type="checkbox"/>	Neonates
<input type="checkbox"/>	Prisoners Attach - Inclusion of Prisoners Supplement

<input type="checkbox"/>	Inpatients
<input type="checkbox"/>	Outpatients
<input type="checkbox"/>	Healthy Volunteers
<input type="checkbox"/>	Staff of UCSF/affiliated institution

C. Eligibility Criteria:

1. General description of subject population(s):

2. [Inclusion Criteria:](#)

3. [Exclusion Criteria:](#)

D. How (chart review, additional tests/exams for study purposes), when and by whom will eligibility be determined?

E. Are there any inclusion or exclusion criteria based on <i>gender, race</i> or <i>ethnicity</i> ? If “Yes,” please explain the nature and rationale for the restrictions below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
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F. Populations Likely to be Vulnerable to Coercion or Undue Influence:

1. List subject groups who are likely to be vulnerable to coercion or undue influence, such as mentally disabled persons, economically or educationally disadvantaged persons, or investigators’ staff or students. **Omit *minors, those unable to consent for themselves, and prisoners* (who are covered by separate Supplements); for *pregnant women, fetuses, and neonates, see section G below*:**

2. Explain why it is appropriate to include the groups listed above in this particular study:

3. Describe **additional** safeguards that have been included in the study to protect the rights and welfare of these subjects and minimize coercion or undue influence. For example, you might provide competence evaluations (specify) for the mentally disabled, payment amounts calibrated to be noncoercive for the financially disadvantaged, extra-careful evaluations of subjects’ understanding of the study, advocates to be involved in the consent process, or use flyers to recruit subjects instead of directly approaching staff or students:

G. Pregnant Women, Human Fetuses, and Neonates:
Identify all sections of 45 CFR 46 Subpart B (see [Chart](#)) under which you believe the research falls and provide study-specific information showing why the research falls within those sections:

PART 7: RECRUITMENT

A. Please review CHR Recruitment Guidelines for more information about acceptable recruitment methods. Note that all advertisements, whether posted or broadcast, and all correspondence used for purposes of recruitment require CHR review and approval before they are used. Check all that apply:							
<input type="checkbox"/>	Study investigators recruit their own patients directly and/or nurses or staff working with researchers approach patients. Please explain in Section B.						
<input type="checkbox"/>	Study investigators send a CHR-approved letter to colleagues asking for referrals of eligible patients interested in the study. The investigators may provide the referring physicians a CHR-approved Information Sheet about the study to give to the patients. If interested, the patient will contact the PI. Or, with documented permission from the patient, the PI may be allowed to talk directly with patients about enrollment. Attach letter for review.						
<input type="checkbox"/>	Study investigators provide their colleagues with a “Dear Patient” letter describing the study. This letter can be signed by the treating physicians and would inform the patients how to contact the study investigators. The study investigators may not have access to patient names and addresses for mailing. Attach letter for review.						
<input type="checkbox"/>	Advertisements, notices, and/or media used to recruit subjects. The CHR must first approve the text of these, and interested subjects will initiate contact with study investigators. Attach ads, notices, or media text for review. In Section B, please explain where ads will be posted.						
<input type="checkbox"/>	Study investigators request a Waiver of Consent/Authorization for recruitment purposes. This waiver is an exception to the policy but may be requested in circumstances such as: <table border="1" data-bbox="162 651 1536 829"> <tr> <td><input type="checkbox"/></td> <td>Minimal risk studies in which subjects will not be contacted (i.e., chart review only);</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Review of charts is needed to identify prospective subjects who will then be contacted. (Explain in Waiver form);</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Large-scale epidemiological studies and/or other population-based studies when subjects may be contacted by someone other than personal physician. (Explain in Waiver form.)</td> </tr> </table>	<input type="checkbox"/>	Minimal risk studies in which subjects will not be contacted (i.e., chart review only);	<input type="checkbox"/>	Review of charts is needed to identify prospective subjects who will then be contacted. (Explain in Waiver form);	<input type="checkbox"/>	Large-scale epidemiological studies and/or other population-based studies when subjects may be contacted by someone other than personal physician. (Explain in Waiver form .)
<input type="checkbox"/>	Minimal risk studies in which subjects will not be contacted (i.e., chart review only);						
<input type="checkbox"/>	Review of charts is needed to identify prospective subjects who will then be contacted. (Explain in Waiver form);						
<input type="checkbox"/>	Large-scale epidemiological studies and/or other population-based studies when subjects may be contacted by someone other than personal physician. (Explain in Waiver form .)						
<input type="checkbox"/>	Direct contact of potential subjects who have previously given consent to be contacted for participation in research. Clinic or program develops a CHR-approved recruitment protocol that asks patients if they agree to be contacted for research (a recruitment database) or consent for future contact was documented using the consent form for another CHR-approved study. Please explain in Section B.						
<input type="checkbox"/>	Study investigators list the study on the UCSF Clinical Trials Seeking Volunteers web page or a similarly managed web site. Interested subjects initiate contact with investigators.						
<input type="checkbox"/>	Study investigators recruit potential subjects who are unknown to them. Examples include snowball sampling, use of social networks, direct approach in public situations, random digit dialing. Please explain in Section B.						

B. Provide detail in the space below (i.e., how, when, where and by whom are potential subjects approached?).

PART 8: INFORMED CONSENT PROCESS

A. Check all that apply:					
<input type="checkbox"/>	Signed consent will be obtained from subjects and/or parents (if subjects are minors),				
<input type="checkbox"/>	Verbal consent will be obtained from subjects, using an: <table border="1" data-bbox="162 1459 1536 1564"> <tr> <td><input type="checkbox"/></td> <td>Information sheet (attach)</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Script (attach)</td> </tr> </table>	<input type="checkbox"/>	Information sheet (attach)	<input type="checkbox"/>	Script (attach)
<input type="checkbox"/>	Information sheet (attach)				
<input type="checkbox"/>	Script (attach)				
<input type="checkbox"/>	Signed consent will be obtained from surrogates Attach - Surrogate Consent Supplement				
<input type="checkbox"/>	Informed consent will not be obtained. Attach - either the Waiver of Consent/Authorization or the Emergency Waiver of Consent Supplement as appropriate.				

B. In the space below, describe *how, where, when* and *by whom* informed consent will be obtained. How much time will prospective subjects be given to consider study participation? If special subject populations will be included, be sure to describe any [additional plans for obtaining consent from particular populations](#). Justify any plans to use verbal consent instead of signed consent.

C. How will you make sure subjects understand the information provided to them?

D. Subjects Who Do Not Read, Speak, or Understand English.	
1. If you will enroll subjects who are unable to Read, Speak or Understand English, what method will you use to obtain consent? <i>Preferred Method</i> should be used if a substantial number of prospective subjects are expected to be non-English speakers. See Those Who Do Not Read, Speak or Understand English for details of methods.	
<input type="checkbox"/>	<i>Preferred Method</i> —Consent form and other study documents will be available in the subject’s primary language. Personnel able to discuss participation in the patient’s language will be present for the consent process.
<input type="checkbox"/>	<i>Short-Form</i> —A qualified interpreter will translate the consent form verbally, and subjects will be given the Experimental Subject’s Bill of Rights in their primary language, following instructions in Those Who Do Not Read, Speak or Understand English for required witnessing and signatures.
2. How will you maintain the ability to communicate with non-English speakers throughout their participation in the study?	

PART 9: FINANCIAL CONSIDERATIONS

A. Payments to Subjects:		
1. Will subjects receive payments or gifts for study participation? If “Yes,” please review CHR Subject Payment Guidelines and complete the following:		<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Payments will be (check all that apply):	<input type="checkbox"/> Cash <input type="checkbox"/> Check <input type="checkbox"/> Other (describe below)	
3. Please describe the schedule and amounts of payments, including the total subjects can receive for completing the study. If deviating from recommendations in Subject Payment Guidelines, include specific justification below.		

B. Costs to Subjects: Will subjects or their insurance be charged for any study procedures? If “Yes,” describe those costs below and explain why it is appropriate to charge those costs to the subjects.	<input type="checkbox"/> Yes <input type="checkbox"/> No

C. Treatment and Compensation for Injury: The investigators are familiar with and will follow the University of California policy and (if applicable) Veteran’s Affairs policy regarding treatment and compensation for injury. If subjects are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California, by the Department of Veteran’s Affairs (for subjects eligible for veteran’s benefits, if the SF VAMC is a study site), or by the study sponsor, if any, depending on a number of factors . The University does not normally provide any other form of compensation for injury.
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PART 10: [BIBLIOGRAPHY](#)

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PART 11: ATTACHMENTS

Please list Attachments, Supplements and Appendices	Version number(s) or date(s)