

UCSF
 COMMITTEE ON HUMAN RESEARCH
 FULL COMMITTEE 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](#)

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 Full Committee Application <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		
<u>CTSI CRC Sites</u> (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 Critical 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

<input type="checkbox"/> Departmental Review*** <input type="checkbox"/> Other: ____
* Specific to this study. ** Required prior to final CHR approval for oncology studies. *** Submit a copy of the signed Departmental Scientific Review form .

D. Key Personnel: All [key personnel](#) including the PI and Co-PI must be listed below along with a brief statement of their [qualifications](#) and study role(s). *If the SF VAMC is a study site*, please identify the principal VAMC investigator, unless already listed as PI or Co-PI above. For questions regarding the VAMC application process, please contact the VA Clinical Research Office at 221-4810 ext.4655. **Please note:** All Key Personnel at UCSF or affiliated sites must complete the [UCSF Collaborative Institutional Training Initiative \(CITI\) online module](#)

Investigators and other personnel [and institution(s)]:	Qualifications:	Study role(s):

E. Statement of Financial Interest: Does the PI or any investigator have any financial interests related to this clinical study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, Attach Disclosure Of Investigators' Financial Interests Supplement	

F. Drugs, Devices and Biologics:

List any drugs and/or biologics under investigation, and IND status*:	name	IND#*, "pending" or " exempt "
List any devices under investigation and IDE status*:	name	IDE#*, "pending" or " exempt "
<input type="checkbox"/> Non-Significant Risk Determination Requested Attach - NSR Supplement		
* Verification of IND/IDE numbers: If the sponsor's protocol does not list the IND/IDE number, your application must include documentation from the sponsor or FDA identifying the IND/IDE number for this study.		
Who holds the IND/IDE?	<input type="checkbox"/> Sponsor <input type="checkbox"/> Investigator:**	
** Investigators who hold an IND/IDE are responsible for knowing and following FDA regulatory requirements for sponsors. See HRPP Guidance on Investigational New Drugs and Biologics or Investigational Devices . Consultation and advice are available through CTSI RKS, Regulatory Knowledge and Support Service .		
Are investigational drugs or biologics controlled by a pharmacy? Contact information for investigational drug pharmacists is in HRPP IND guidance .	<input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," identify the pharmacy/ies: If "No," describe your plan for control of the test article:	
Are investigational drugs, devices, or biologics (test articles) controlled by the Principal Investigator? See IDE Guidance .	<input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," describe your plan for control of the test article:	
Are investigational drugs, devices, or biologics prepared or manufactured in UCSF research labs?	<input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," identify the lab:	

G. Other Approvals/Regulated Materials: Does this study require approval or authorization from any of the following regulatory committees, or involve the use of the regulated materials listed below? Follow the hyperlinks for more information. If "Yes," complete the applicable section(s) below.	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Biological Safety Committee	BUA #:
<input type="checkbox"/> Human Gene Transfer/Recombinant DNA Research	Attach - Human Gene Transfer / Recombinant DNA Research

		<u>Supplement</u>
<input type="checkbox"/>	<u>Institutional Animal Care and Use Committee</u>	IACUC #:
	<input type="checkbox"/> Xenotransplantation	
<input type="checkbox"/>	<u>Controlled Substances</u>	
<input type="checkbox"/>	<u>Human Stem Cells</u>	Attach - <u>Human Stem Cell Supplement</u>
<input type="checkbox"/>	<u>Radiation Safety Committee</u>	RUA #:

H. Clinical Trial Registration:

Public Law 110-85 requires registration of clinical trials. The International Committee of Medical Journal Editors (ICMJE) also requires registration of clinical trials in order for results to be published in member biomedical journals. Additional information, including guidance on the UCSF registration process for ClinicalTrials.gov at UCSF, and the *definition of a clinical trial* for purposes of registration can be found at [Office of Research News, Vol. 8, No. 2.](#)

Please provide one of the following:

ClinicalTrials.gov "NCT" number for this trial: _____, or: Registration pending
 This is not a clinical trial; registration not required

Clinical trials are required to be registered *before the enrollment of the first subject*, but not prior to CHR approval.

I. Principal Investigator's Certification:

- I certify that the information provided in this application is complete and correct.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of UCSF and affiliated institutions where this study will be conducted, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research.
- I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the CHR-approved protocol.
- I will not modify this CHR-certified protocol or any attached materials without first obtaining CHR approval for an amendment to the previously approved protocol.
- I assure that the protected health information requested, if any, is the minimum necessary to meet the research 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

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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. <u>Design</u>	
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;	<input type="checkbox"/> Yes <input type="checkbox"/> No

schools; local government agencies; local businesses; or other local organizations?	
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	

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:

- Calculation of descriptive statistics such as mean, median, SD, range, tallies.*
- Examination of graphs such as outcome vs. time, scatterplots of two variables, Kaplan-Meier curves.*
- Estimation of differences between two groups with comparison by t-test or Mann-Whitney test.*
- Estimation and testing of within-person changes by matched t-test or Wilcoxon signed-rank test.*
- Multiple linear regression, logistic regression, or Cox proportional hazards regression.*
- Repeated measures models (usually requires the help of a statistician).*

For qualitative research, briefly describe how qualitative data will be analyzed.

H. Sample Size: Indicate how many subjects will be studied and why this number was chosen.

PART 3: PROCEDURES

A. Check all that apply.

[Human Biological Specimen Banking](#) **Attach - [Banking Supplement](#)**

[Genetic Testing](#) [HIV 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.

D. Will any interviews, questionnaires, surveys or focus groups be conducted for the study? If “Yes,” please list any standard instruments used for this study and attach any non-standard instruments.	[]Yes []No

E. Will subjects undergo any study procedures or tests off-site by non-UCSF personnel? If “Yes,” please explain.	[]Yes []No

F. Will subjects or their health care provider be given the results of any experimental tests that are performed for the study? If “Yes,” please describe the tests, provide a rationale for providing subjects with the experimental test results and explain what, how and by whom subjects and their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.	[]Yes []No

PART 4: [ALTERNATIVES](#)

A. Describe the standard or usual care or activities at UCSF (or study site) that are available to prospective subjects who do not enroll in this study.

B. Describe other alternatives to study participation that are available to prospective subjects.

C. Is study drug or treatment available off-study? If “Yes,” discuss this in the consent form.	[]Yes []No []N/A
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PART 5: RISKS AND BENEFITS

<p>A. Risks and Discomforts:</p> <p>1. Describe the risks and discomforts of any investigational or approved drugs, devices and procedures being used or assigned for study purposes. Describe the expected frequency of particular side effects. If subjects are restricted from receiving standard therapies during the study, please also describe the risks of those restrictions.</p> <p>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.</p>
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B. Data and Safety Monitoring Plan (DSMP): *All interventional studies involving more than minimal risk must include a DSMP.* A DSMP is a plan established to assure that each research study has a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data. The DSMP should indicate specifically whether or not there will be a formal Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC).
Note: Most, but not all studies (i.e., non-interventional studies) undergoing full committee review will require a DSMP. **For what to include in a DSMP see [DSMP Information Sheet for Principal Investigators](#).**

C. Adequacy of Resources:
Principal Investigators must have the necessary resources required to conduct the proposed research in a way that assures the rights and welfare of participants are adequately protected. Depending on the nature of the research study, investigators should consider the proximity or availability of critical resources that may be essential to the safety and welfare of participants. For example, the proximity of an emergency facility for care of participant injury, or availability of psychological support after participation, or resources for participant communication, such as language translation services.

Have you or will you undergo formal resource review (e.g., VAMC, SFGH, CCRC) prior to study implementation?	[] Yes [] No
<i>If yes, please specify entity providing review:</i>	
<i>If no, please describe below the resources you have in place to conduct this study in a way that assures protection of the rights and welfare of participants:</i>	

D. Confidentiality and Privacy: Privacy concerns people, whereas confidentiality concerns data. Specifically, confidentiality refers to the researcher’s plan to handle, manage and disseminate the participant’s identifiable private information. Privacy refers to a person’s wish to control the access of others to themselves. **Address each of the following privacy issues 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"/> Facial Photos/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 identifiers marked in the above section. Check all that apply:

Are 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?	HIPAA regulations apply. The identifiers marked in section D.4 are PHI.
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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?	

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

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 <i>minors, those unable to consent for themselves, and prisoners</i> (who are covered by separate Supplements); for <i>pregnant women, fetuses, and neonates</i>, 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:

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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:

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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. <i>Please explain in Section B.</i>						
<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. <i>Attach letter for review.</i>						
<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. <i>Attach letter for review.</i>						
<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. <i>Attach ads, notices, or media text for review. In Section B, please explain where ads will be posted.</i>						
<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" style="width: 100%; margin-left: 20px;"> <tr> <td style="width: 5%; text-align: center;"><input type="checkbox"/></td> <td>Minimal risk studies in which subjects will not be contacted (i.e., chart review only);</td> </tr> <tr> <td style="text-align: center;"><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 style="text-align: center;"><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. <i>Please explain in Section B.</i>						
<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. <i>Please explain in Section B.</i>						

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

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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),
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<input type="checkbox"/>	Verbal consent will be obtained from subjects, using an:
<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? *Preferred Method* 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: Yes No

2. Payments will be (check all that apply): Cash Check 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 compare subjects’ costs to the costs associated with alternative care off-study. Finally, explain why it is appropriate to charge those costs to the subjects. Yes 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.

PART 10: BIBLIOGRAPHY

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PART 11: ATTACHMENTS

Please list <u>Attachments, Supplements and Appendices</u>	Version number(s) or date(s)