2. Patient Rights Form – SAMPLE

(Name of Project)

Study Participant Rights

As a participant in the XXYYZZ project, the data on chemical levels in your body will be your property. You will have a chance to share your data with others through scientific publications and public outreach projects if you wish. What you do with your data is your decision. Your rights as a participant in this study are listed below.

Being part of this study is your personal decision. You have the right to withdraw yourself and your data from the study at any time. You can do this simply by expressing to Dr. XXXX your desire to withdraw, by telephone at (XXXX). If you wish your data to be withdrawn from the study, Dr. XXX will destroy your entire file, or mail the file to you, whichever you prefer. Your agreement to participate in this study means that you are at least initially willing to allow XXYYZZ to use your data in publications in which your name will not be revealed. Your right to withdraw means that you can, at any time, change your mind and even decline anonymous inclusion in publications.

If you wish, you can be part of a number of sharing and outreach opportunities planned as follow-up to this XXYYZZ project. You have the right to decline participation in any or all of these activities and projects, including sharing and discussion activities, and public outreach and media projects.

If you wish, you can allow your name to be used in public outreach efforts at any level with which you are comfortable. You have the right to remain anonymous throughout the study and throughout any or all of the follow-up sharing, discussion, and public outreach projects.

I have read these rights, and understand them.

Project participant printed name_____

Project participant signature_____Date_____

Surrogate signature_____date_____

Relationship if signed by surrogate_____

Expedited application form (UCSF)

UCSF
COMMITTEE ON HUMAN RESEARCH
REVISED EXPEDITED REVIEW APPLICATION
(BETA VERSION)

Please date form: __

General Instructions | View Complete Set of Linked Instructions | Frequently Asked Questions

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 *one*):	[ ]PI only [ ]PI and Co-PI [ ]PI and Additional Contact Person	

Study Title:	**Application Type:**
	[ ]New Expedited Review Application Category No.: [ ]Response to "Contingent" or "Return" letter [ ]Modification [ ]Renewal Current CHR #: __ Expiration date: __

Sites (Check all that apply):

[ ]UCSF [ ]SFGH [ ]VAMC [ ]Fresno [ ]Cancer Center [ ]UC Berkeley
[ ]GCRC (Moffitt/Mt. Zion) [ ]GCRC (SFGH) [ ]PCRC [ ]Foreign Country
[ ]Other(s):

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. Check all that apply:

Type of funding	Source of funding	Funds will be awarded to/through:
[ ]Contract/Grant [ ]Subcontract [ ]Drug/device donation [ ]Student project [ ]Other: __ Have funds been awarded? [ ]Yes [ ]Pending [ ]No Award No.: __	[ ]Federal Government [ ]Other Gov. (e.g., State, local) [ ]Industry* [ ]Other Private [ ]Campus/UC-Wide program [ ]Departmental Funds [ ]Other: Sponsor Name: __	Dept./ORU: *Institution* — *Federal Wide Assurance (FWA) No.* [ ]UCSF ..... 00000068 [ ]Blood Centers of the Pacific ..... 00002111 [ ]Gallo Institute ..... 00000304 [ ]Gladstone Institute ..... 00000087 [ ]Goldman Institute on Aging..... 00002525 [ ]NCIRE ..... 00000256 [ ]S.F. Dept. of Public Health ..... 00000162 [ ]VA Research Office 00000280

***UCSF (or affiliate) financial contact person for IRB review recharge:**	
Grant Title and PI (if different from above):	

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

C. Key Personnel: All key personnel including the PI and Co-PI must be listed below along with a brief statement of their qualifications. *If the SF VAMC is a study site*, please identify the principal VAMC investigator, unless already listed as PI or CoPI above. For questions regarding the VAMC application process, please contact the VA Clinical Research Office at 221-4810 ext.4655.	
Investigator (and institution):	Qualifications:

D. 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.		[ ]Yes [ ]No
[ ]	Biological Safety Committee	BUA #:
[ ]	Human Stem Cells	Submit stem cell supplement

E. Scientific Merit Review: This study has received or will receive scientific merit review from (check all that apply):
[ ]NIH [ ]Cancer Center* [ ]GCRC or PCRC [ ]SFVAMC [ ]Dept. Review [ ]Other:
*Required prior to final CHR approval for oncology studies.

F. Statement of Financial Interest: Do you or the other investigators have a financial interest in the outcome of this study? If "Yes," please describe below and describe briefly in Purpose and Background section of the consent form.	[ ]Yes [ ]No

G. 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.

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. Purpose (Specify the hypotheses, aims and/or objectives.) Space limit: quarter page

C. Background (Summarize previous studies. Explain rationale for the proposed investigation.) Space limit: half page

D. Design Please describe *general* study design: Space limit: quarter page

E. Data Analysis (How and by whom will data be analyzed?) Space limit: quarter page

PART 3: PROCEDURES

A. Check all that apply.

[ ]Biological Specimen Banking [ ] 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. How much time will be required of the subjects, per visit and in total for the study?

D. 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	[ ]Yes [ ]No

instruments.	

E. Will any procedures or tests be done off-site by non-UCSF personnel? If "Yes," please explain.	[ ]Yes [ ]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.	[ ]Yes [ ]No [ ]N/A

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:

B. Confidentiality and Privacy: Describe the consequences to subjects of a loss of privacy (e.g., risks to reputation, insurability, other social risks):

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

[ ] Names	[ ] Social Security Numbers	[ ] Device identifiers/Serial numbers
[ ] Dates	[ ] Medical record numbers	[ ] Web URLs
[ ] Postal address	[ ] Health plan numbers	[ ] IP address numbers
[ ] Phone numbers	[ ] Account numbers	[ ] Biometric identifiers
[ ] Fax numbers	[ ] License/Certificate numbers	[ ] Photos and comparable images
[ ] Email address	[ ] Vehicle id numbers	[ ] Any other unique identifier

[ ] None of the 18 identifiers listed above

2. 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: [ ] Derived from a medical record? ***Please identify source***: [ ] Added to the hospital or clinical medical record? [ ] Created or collected as part of health care? **[ ]** Used to make health care decisions?	**HIPAA regulations apply.** The information identified in section B.1. above is PHI.

[ ] Obtained from the subject, including interviews, questionnaires? [ ] Obtained from a foreign country or countries only? [ ] Obtained from records open to the public? [ ] Obtained from existing research records? [ ] None of the above.	**HIPAA regulations do not apply.** The information identified in section B.1. 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.)

3. 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
[ ] The study sponsor: ***please indicate***:
[ ] The US Food & Drug Administration (FDA)
[ ] Others: ***please indicate***:
[ ] A Foreign Country or Countries

4. Data Security: Please indicate how study data is kept secure. Check all that apply:

[ ] Data is coded; data key is destroyed at end of study or ***provide date***:
[ ] Data is coded; data key is kept separately and securely
[ ] Data is kept in locked file cabinet
[ ] Data is kept in locked office or suite
[ ] Electronic data are protected with a password
[ ] Data is stored on a secure network

5. 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.

6. 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.	[ ]Yes [ ]No

B. Benefits: **1.** Are there potential direct benefits to study subjects? If "Yes," please describe below.	[ ]Yes [ ]No

2. What are the potential benefits to society?

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

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?	

B. Types of Subjects: Check all that apply. Click on links for additional instructions.	
[ ]	Minors: Complete and attach "Inclusion of Minors" Supplement
[ ]	Subjects unable to provide informed consent
[ ]	Subjects with diminished capacity to provide informed consent
[ ]	Subjects unable to read or speak English
[ ]	Pregnant Women
[ ]	Fetuses
[ ]	Neonates
[ ]	Prisoners: Complete and attach "Inclusion of Prisoners" Supplement
[ ]	Inpatients
[ ]	Outpatients
[ ]	Normal Volunteers
[ ]	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 *gender*, *race* or *ethnicity*? If "Yes," please explain the nature and rationale for the restrictions below. [ ]Yes [ ]No

PART 7: RECRUITMENT

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:

[ ]	Study investigators recruit their own patients directly and/or nurses or staff working with researchers approach patients. ***Provide detail in the space below*** *(i.e., how, when and where potential subjects are approached).*

[ ]	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.
[ ]	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.
[ ]	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.
[ ]	Study investigators request a Waiver of Consent/Authorization for recruitment purposes. This waiver is an exception to the policy but may be requested in exceptional circumstances such as:
[ ] [ ] [ ]	Minimal risk studies in which subjects will not be contacted (i.e., chart review only); Review of charts is needed to identify prospective subjects who will then be contacted (explain in protocol); Large-scale epidemiological studies and/or other population-based studies when subjects may be contacted by someone other than personal physician (justify in protocol).
[ ]	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. ***Provide detail in the space below*** *(i.e., how, when and where potential subjects are approached).*

[ ]	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.
[ ]	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 below*:**

[ ]	This study does not involve subject contact for recruitment (i.e., records review, use of specimens).

PART 8: INFORMED CONSENT PROCESS

A. Check all that apply:

[ ] Signed consent will be obtained from subjects
[ ] Verbal consent will be obtained from subjects, using an
    [ ] Information sheet
    [ ] Script
[ ] Signed consent will be obtained from surrogates
[ ] Informed consent will not be obtained

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.

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

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 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: REFERENCES

PART 11: ATTACHMENTS

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