

**CALIFORNIA PACIFIC MEDICAL CENTER
 INSTITUTIONAL REVIEW BOARD
 Exempt Review Application form**

PLEASE TYPE

No: _____
 (Staff use only)

Title Of Project:		
Principal Investigator: <i>*The Principal Investigator must be a medical staff member or an employee of CPMC. He or she is considered the responsible party for legal and ethical performance of the project.</i>	Sutter Affiliation:	Dept.:
Mailing Address:	Phone Number: Fax No: E-mail address:	
Sub- investigator (s):		
Name:	Affiliation:	Dept.:
Name:	Affiliation:	Dept.:
Name:	Affiliation:	Dept.:
Anticipated Project Period: From Date: To Date:	Total Expected Enrollment at this Site: Recruitment Source (s):	
Funding agency or sponsor:		

Check affiliate site where research will be conducted:

GREATER BAY AREA

- ALTA BATES SUMMIT MEDICAL CENTER, BERKELEY & OAKLAND
- CALIFORNIA PACIFIC MEDICAL CENTER, SAN FRANCISCO
- EDEN MEDICAL CENTER, CASTRO VALLEY
- MARIN GENERAL HOSPITAL, GREENBRAE
- MILLS-PENINSULA HEALTH SERVICES, BURLINGAME/SAN MATEO
- NOVATO COMMUNITY HOSPITAL, NOVATO
- PALO ALTO MEDICAL FOUNDATION, PALO ALTO
- SANTA CRUZ MEDICAL FOUNDATION
- ST. LUKE'S HOSPITAL, SAN FRANCISCO
- SUTTER DELTA MEDICAL CENTER, ANTIOCH
- SUTTER MATERNITY & SURGERY CENTER OF SANTA CRUZ
- SUTTER MEDICAL CENTER OF SANTA ROSA
- SUTTER REGIONAL MEDICAL FOUNDATION
- SUTTER SANTA CRUZ
- SUTTER SOLANO MEDICAL CENTER, VALLEJO
- SUTTER TRACY COMMUNITY HOSPITAL, TRACY

Greater Sacramento Valley/Foothills

- SUTTER AMADOR HOSPITAL, JACKSON
- SUTTER AUBURN FAITH HOSPITAL, AUBURN
- SUTTER DAVIS HOSPITAL, DAVIS
- SUTTER MEDICAL CENTER, SACRAMENTO
- SUTTER NORTH MEDICAL FOUNDATION, MARYSVILLE/YUBA CITY
- SUTTER ROSEVILLE MEDICAL CENTER, ROSEVILLE

Central Valley

- MEMORIAL HOSPITAL, LOS BANOS
- MEMORIAL MEDICAL CENTER, MODESTO
- SUTTER GOULD MEDICAL FOUNDATION, MODESTO

North Coast

- SUTTER COAST HOSPITAL, CRESCENT CITY

Clearlake

- SUTTER LAKESIDE HOSPITAL, CLEARLAKE

Other Sutter Affiliates:

1) This research qualifies for federal exempt review category number:

Include justification for chosen federal category number:

2) **Tissue/Blood Banking:** Will tissue or serum samples be sent outside of the institution?

- Yes No

3) Does the research protocol involve questionnaire(s)?

- Yes No If yes, please submit questionnaire(s).

Do questionnaires involve special sensitivity (e.g., drugs/alcohol abuse; sexual behavior)?

- Yes No If yes, please submit questionnaire(s).

4) **Conflict of Interest:** Has the Principal Investigator and/or Co/Sub investigator(s) completed the conflict of interest form for the current year?

- Yes No If No, please contact Research Services Office at (415)600-3687.

5) **Education of Human Subject Protection:** Has the Principal Investigator and/or Co/Sub investigator(s) taken a course about Human Subject Protections or Responsible Conduct of Research?

- Yes No If No, please refer to “List of Training Options in Human Subjects Protections”, pages 3 & 4, IRB Submission Requirements Checklist or call the IRB office at (415)600-3688 or 600-3709.

Has the research staff (s) taken the same course?

- Yes No If No, please refer to “List of Training Options in Human Subjects Protections”, pages 3 & 4, IRB Submission Requirements Checklist or call the IRB office at (415)600-3688 or 600-3709.

6) Give a brief description of this study.

- 7) Will any subjects be contacted for purposes of this study?
 Yes No If yes, describe the contact process.
- 8) Will subjects be completely anonymous?
 Yes No If not, how will their identities be coded?
 How long and in what way will records be retained?
- 9) Who will have access to study data?
- 10) Will there be any data collection sheets used for study purposes?
 Yes No If yes, please submit one copy of each.

Administrative Acknowledgement of the Protocol

My signature acknowledges that I have reviewed the attached protocol and support its implementation.

Principal Investigator's Department Chair's Signature

Date

Principal Investigator's Assurance

My signature below constitutes my assurance that:

I certify that the information provided in this application is complete and correct. I understand that CPMC IRB approval does not indicate institutional authorization to conduct this research study. I will obtain appropriate approval from all institutions involved.

Principal Investigator's Signature

Date

CATEGORIES EXEMPT FROM IRB REVIEW

From: Code of Federal Regulations Regarding Protection of Human Subjects, 45 CFR 46.101(b) - Effective June 18, 1991

Research activities in which the only involvement of human subjects will be in one or more of the following categories may qualify as Exempt if:

1. Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 2. Research involves the use of educational tests, (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: [(i) Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.] *
 3. Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal status(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 4. Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
 5. Research and demonstration projects which are conducted by or subject to the approval of department of agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in method or levels of payment for benefits or services under those programs.
 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level, and for a use, found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food and Safety Inspection Service of the USDA.
- * The exemption does not apply to children except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

CERTIFICATION OF EXEMPT STATUS

On the basis of the information presented above, this research activity qualifies as EXEMPT from review by the Institutional Review Board of CPMC.

Chair, Institutional Review Board

Date

cc: CPMC Medical Records

DENIAL OF EXEMPT STATUS

On the basis of the information presented above, this research activity does not qualify for exempt status, and an application written in accordance with the CPMC IRB Guidelines should be submitted.

Chair, Institutional Review Board

Date