

Policies and Procedures



Institutional Authority

The California Health and Human Services Agency (CHHSA) established the Committee for the Protection of Human Subjects (CPHS), an institutional review board, in July 1976. The Health and Human Services Agency is bound by the terms of the Federalwide Assurance (FWA) 00000681 signed in June 2001 with the U.S. Department of Health and Human Services, Office for Human Research Protections. The CPHS is the only institutional review board empowered by the California Health and Human Services Agency. The Federalwide Assurance requires the CPHS to adopt these policies and procedures.

Purpose of the CPHS

CPHS reviews all research involving human participants conducted or supported by the CHHSA and all research using private information held by CHHSA. The CPHS conducts reviews of research in compliance with Title 45, Part 46 of the Code of Federal Regulations (Common Rule) and when applicable, Title 21, Parts 50 and 56 of the Code of Federal Regulations (FDA Regulations). The CPHS also reviews the eligibility of research for a waiver of (or alteration of) patient authorization for release of protected health information under the Health Insurance Portability and Accountability Act (HIPAA).

Principles Governing the CPHS

CPHS are governed by the ethical principles delineated in The Belmont Report, issued by the Department of Health, Education, and Welfare in April, 1979. These include:

Respect for Persons

“Respect for persons incorporates at least two ethical convictions: first, those individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.”

Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.”

Justice

The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reason directly related to the problem being studied. Finally, whenever research supported by

public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Authority of the CPHS

Scope of Authority

Jurisdiction - all research conducted by, funded by (regardless of original source), or using personally identifiable data held by the California Health and Human Services Agency and its 13 component departments (see below). Jurisdiction also includes all research involving subjects for whom the California Health and Human Services Agency (CHHSA) or its components have direct responsibility, such as patients in State hospitals.

California Department of Aging
California Department of Child Support Services
California Department of Community Services and Development
California Department of Developmental Services
California Department of Health Care Services
California Department of Managed Health Care Services
California Department of Public Health
California Department of Rehabilitation
California Department of Social Services
California Department of State Hospitals
Emergency Medical Services Authority
Managed Risk Medical Insurance board
Office of Statewide Health Planning and Development

Definition of Research - as defined in §46.102 of the Code of Federal Regulations, research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Reporting Responsibilities - the CPHS will report the following serious events to the Secretary of the California Health and Human Services Agency, the U.S. Office of Human Research Protection, the funding agency (whether federal, state, or private), and the responsible official of the project:

- Serious, unexpected adverse health effects for subjects or the general public.
- Violations of ethical research behavior (e.g., failure to provide informed consent or protect confidentiality).
- Research fraud (e.g., misrepresentation of study findings and fabrication of data).
- Serious deviations from approved study protocols without prior CPHS approval.

Reciprocity with Other Institutions

The CPHS will engage in formal agreements to serve as the institutional review board for other institutions in California with current Federalwide Assurances in place. Reciprocity arrangements to enable other institutional review boards to approve projects for the CPHS are not currently in place but may be considered in the future.

California Health and Human Services Agency (CHHSA) Responsibilities

- The Secretary of CHHSA is the signatory of CHHSA's Federalwide Assurance and shall serve as the authorized Institutional Official. The Secretary is responsible for appointing the CPHS chairperson and CPHS members.
- Provide written assurance of compliance with requirements of 45 CFR 46 in the Federalwide Assurance to the U.S. Department of Health and Human Services.
- Enforce policies requiring that all research conducted or supported by CHHSA and its departments is reviewed and approved by the CPHS, unless otherwise exempted by the CPHS.
- Provide sufficient professional staff to support the activities of the CPHS, including the appointment of a full-time Human Protections Administrator in a permanent civil service position [45 CFR 46.103(b)(2)].
- Provide that CPHS members who are CHHSA employees will have 10% of work duties designated for CPHS activities. For the CPHS Chair, 20% of work duties will be designated for CPHS activities.
- Provide sufficient resources and meeting space to support CPHS activities [45 CFR 46.103(b)(2)].
- Provide adequate training of CPHS staff and members in policies and procedures related to research with human subjects. This shall include support of educational activities related to the design, conduct, and approval of research and access to journals and other research-related materials and attendance at workshops and conferences.
- Support measures to educate researchers about protections for human subjects.
- Maintain open channels of communication between CPHS members, staff, subjects, researchers, and other interested parties both within and outside CHHSA.
- Assure that CHHSA executive staff (e.g., CHHSA's special advisor to the CPHS) is available to provide guidance to the CPHS, department heads and other officials with responsibility for oversight of research.
- Enforce CPHS decisions to disapprove, suspend, or terminate research projects that do not adequately protect the rights and welfare of human subjects. CHHSA will appropriately sanction investigators who do not conduct research in accordance with CPHS requirements and determinations, who violate Federal regulations, or who knowingly compromise the rights and welfare of human subjects.

- CHHSA officials may not approve research involving human subjects if the CPHS has not approved it [45 CFR 46.112].

CPHS Members

Selection and Appointment

Members are appointed by and serve at the pleasure of the Secretary of CHHSA.

Membership must fulfill the requirements of §46.107:

- CPHS must have at least five members, with varying backgrounds and fields of expertise.
- Members must be knowledgeable in the areas of research that the CPHS reviews.
- For review of research involving a vulnerable category of subjects, at least one member must be knowledgeable and experienced in working with that vulnerable population (e.g., a prisoner advocate).
- CPHS shall have at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- CPHS must have at least one member not affiliated with CHHSA directly or through an immediate family member.
- Every effort will be made to ensure that the CPHS has a diverse membership, particularly with respect to race, gender, and cultural background.

Nominations for membership may be submitted to the CPHS Administrator by CHHSA department heads, any CHHSA employee, or members of the public. Such nominations must include the curriculum vitae and a list of references for the person being nominated.

The CPHS Administrator will pre-review all nominations and create a file for the candidate.

The CPHS Administrator will forward nominations to the Chair and Vice-Chair for review. When the Chair determines that appointment of a new member is necessary to maintain compliance with §46.107, to handle increased workload, or upon request of the CHHSA Secretary, the Chair will forward a prioritized list of candidates, with curriculum vitae and reference list, to the CHHSA Secretary.

The following factors may be considered by the Chair when prioritizing candidates:

- Knowledge of general principles of scientific research.
- Expertise in research with special and vulnerable population groups (e.g., women, children, prisoners, welfare recipients, mentally-impaired persons).

- Expertise in research subjects of special importance to the CPHS (e.g., pharmacology, genetics, and social science).
- Ability to represent the needs of vulnerable ethnic and diverse population groups (e.g. ethnic minorities, children, and prisoners).
- Knowledge of the principles of ethical research.
- Ability to represent the research needs of specific CHHSA departments.

Number and Tenure

The CPHS is composed of a maximum of 13 members. CPHS members serve for a three (3) year term contingent upon continued fulfillment of the duties and responsibilities designated in “C” below. Members may be reappointed for additional three (3) year terms at the discretion of the CHHSA Secretary. Members may resign at any time by submitting written notification to the Administrator.

Duties and Responsibilities

Meeting Attendance and Participation members are expected to attend all meetings. Absences at more than one-third of meetings within a 12-month period may constitute grounds for dismissal. Members who cannot attend a meeting are expected to notify the Administrator 10 weeks in advance of the meeting, if possible, and are expected to review and provide feedback to the Administrator about continuing review projects for which they are the designated primary reviewer.

Professional Conduct - members are expected to treat all researchers, regardless of experience or background, with respect and courtesy.

Conflict of Interest - A member shall not participate in the review process for any project, except to provide information requested by the CPHS, in which he or she has a present or potential conflict of interest, including any personal, professional, or financial conflicts. The member should notify the Chair of the conflict of interest and should be absent from the meeting room during the discussion and voting phases of the deliberations, except to provide information requested by the CPHS.

Initial Review - each member will serve as primary reviewer for at least one new project proposal to be assigned by the Administrator for each meeting. In this capacity, the member will review the proposal and contact the principal investigator(s) at least one (1) week before the meeting regarding any substantive concerns and questions. All members are expected to be familiar with all projects under initial review at each meeting and to inform the Administrator if they have any substantive concerns.

Continuing Review - members will review all continuing review applications for which they have served as primary reviewer. For continuing projects eligible for expedited review, the primary reviewer will serve as the sole reviewer, unless otherwise designated by the Chair. Members are expected to complete expedited review within two (2) weeks of receipt of the project proposal. Members will notify the Administrator at least three (3) days in advance of

each CPHS meeting regarding continuing projects for which participation of the principal investigator in the meeting is requested. If a member makes such a determination less than three (3) days before the meeting, the member will be expected to personally notify the principal investigator. All members are expected to be familiar with all projects submitted for continuing review at each meeting, including projects with revisions or reports of unanticipated problems or adverse events. Members should contact the Administrator if they have substantive concerns about any continuing project.

Expedited Review of New Projects - members will carry out expedited review on appropriate new projects in collaboration with the CPHS Chair or Vice Chair. Members are expected to complete expedited review within two (2) weeks of receipt of the project proposal.

Training and Continuing Education - All new members must complete the on-line U.S. Office for Human Research Protection Training Modules, located at <http://ohrp.osophs.dhhs.gov>. New members are paired with an experienced member to review project materials for the first meeting. All members are provided with a copy of the IRB Guidance Materials manual prepared by the CPHS Administrator. Members are expected to read and understand this material. Periodic updates are provided for inclusion in the manual. Members are also provided access to current copies of the journals Human Research Report and IRB Ethics and Human Research, which they are expected to review.

Compensation

CHHSA employees will have 10% of their duties designated for CPHS activities. Members who are not CHHSA employees are not compensated for their participation. Travel and incidental expenses are reimbursed by OSHPD for participating in CPHS meetings and other related activities as approved by the Administrator.

CPHS Chair

Selection and Appointment

- The Chair is selected and appointed by the Secretary of CHHSA.
- The Chair must be a CHHSA employee and have been a member of the CPHS for at least two (2) years.

Tenure

- The Chair serves at the discretion of the Secretary of CHHSA.
- After three (3) years of service, the Chair is eligible for three (3) additional years of service as Chair if reappointed by the Secretary of CHHSA.

Duties and Responsibilities

Assure that the CPHS operates in accordance with the terms of the Federalwide Assurance (shared responsibility with the Administrator) and inform the CHHSA Secretary regarding problems that inhibit the CPHS from fulfilling its functions.

Advise the Secretary of CHHSA regarding appointment of new CPHS members.

Advise researchers both within and outside CHHSA regarding the functioning and use of the CPHS.

Determine projects that need verification of information from source(s) other than the principal investigator, including whether material changes have occurred since the last CPHS review.

Advise the CPHS Administrator regarding assignment of project proposals to members for primary review and daily functioning of the CPHS. The Chair is available to assist the CPHS Administrator in responding to inquiries from researchers and others both within and outside of CHHSA.

Propose policy and procedure changes for the CPHS.

Represent the CPHS at CHHSA meetings, as well as at national meetings.

Chair all meetings of the CPHS. If unable to attend, arrange for this to be performed by the Vice Chair.

The Chair may only vote on project proposals in order to break a tie vote or if the Chair's presence is necessary in order to attain a committee quorum.

Carry out expedited review of appropriate selected project proposals in collaboration with another CPHS member.

Provide education to members regarding recent changes in federal policies or regulations (joint responsibility with CPHS Administrator).

Approve and submit an annual report to the CHHSA Secretary.

Conduct or arrange educational seminars for researchers (shared responsibility with the Administrator).

CPHS Vice-Chair

Selection and Appointment

- The Vice-Chair is selected and appointed by the CPHS Chair with approval of the Secretary of CHHSA.
- The Vice-Chair must have been a member of the CPHS for at least one (1) year. Employment with CHHSA is not a requirement for selection.

Tenure

The Vice-Chair serves at the discretion of the Chair.

Duties and Responsibilities

- Assume responsibilities of the Chair when the Chair is unavailable.
- Participate in expedited review subcommittees when requested by the Chair.

CPHS Administrator

Selection and Appointment

The CPHS administrator is a full-time employee of the State of California who holds the rank of staff services manager I (SSM I).

The CPHS administrator must be selected through appropriate civil service procedures.

The CPHS Administrator is selected by the CPHS Chair in collaboration with the Executive Director, California Health Policy and Data Advisory Commission. The CHHSA Secretary, as the designated institutional official on the Federalwide Assurance, approves the designation of the Human Protections Administrator on the Federalwide Assurance.

Duties and Responsibilities

Assure that the CPHS operates in accordance with the terms of the Federalwide Assurance (shared responsibility with the Chair).

Serve as the primary liaison between CPHS members and the U.S. Office of Human Subject Protection, investigators, and CHHSA officials.

Prepare Secretary's Action Requests (SARs) for membership nominations, and other actions needing CHHSA Secretary's approval.

Assist investigators in the preparation and submission of research applications for CPHS review.

Review research applications prior to distribution to CPHS members and notify researchers if applications are incomplete.

Obtain verification of information about projects from sources other than the principal investigator at the direction of the Chair.

Assign primary reviewers to project proposals submitted for initial review, in consideration of members' areas of expertise, workload, and conflicts of interest. (shared responsibility with the Chair).

Mail materials to CPHS members.

Maintain the CPHS tracking system and records.

Organize logistics for all CPHS meetings.

Prepare minutes for CPHS meetings.

Prepare CPHS correspondence to investigators.

Review requests for exemptions in collaboration with the CPHS Chair

Supervise the staff services analyst and other clerical and support staff in carrying out daily functioning of the CPHS.

Maintain the CPHS website with assistance from the OSHPD webmaster.

Prepare an annual report to the CHHSA Secretary for submission by the Chair.

Conduct or arrange educational seminars for researchers (shared responsibility with the Chair).

Inform primary reviewers of concerns expressed by other members regarding research proposals.

Approve expense reimbursements for CPHS members under the supervision of the Executive Director, California Health Policy and Data Advisory Commission.

Operations of the CPHS

Meetings

Schedule - The CPHS meets on the first Friday of even-numbered months (February, April, June, August, October, and December) from 8:30 a.m. to 4:00 p.m. Additional meetings may be scheduled and meetings may be rescheduled upon determination of the Chair and with appropriate public notice.

Location - Meetings are held at the following location: 400 R Street, Room TBD, Sacramento, CA 95814.

Open Meeting Act - Meetings are conducted in compliance with the Bagley-Keene Act. Copies of all materials distributed to members and discussed at the meeting must be available for public viewing. The agenda must be posted at least ten (10) calendar days before the meeting, and cannot be changed less than ten (10) days before the meeting except in extraordinary circumstances as permitted by the Bagley-Keene Act.

Quorum - A quorum is defined as attendance by more than 50% of members, with at least one of the present members having primary concerns in nonscientific areas. If a quorum will not be present, the Administrator will select an alternate Friday to convene the meeting. This alternate date must be before the expiration of project approvals.

Committee Decisions - The CPHS can take the following actions upon review of project proposals under the Common Rule and waivers of patient authorization under HIPAA:

- Approved.
- Approval deferred pending specified minor revisions requiring only expedited review by the CPHS Chair and the project's primary reviewer.
- Approval deferred pending specified major revisions requiring a subsequent full committee review.
- Tabled pending resolution of significant issues will require full committee review of entire project.
- Disapproved.

Preparation and Posting of Agenda - The CPHS Administrator prepares and e-mails the meeting agenda to the OSHPD webmaster at least 17 days before the meeting, since the OSHPD webmaster requires five (5) working days to post the agenda. CPHS staff sends printed meeting agendas to all people on the CPHS mailing list at least ten (10) calendar days before the meeting. Alternatively, electronic copies of agendas will be sent upon request. The agenda will contain the following items in sequence:

- Location, date and time of the meeting.
- Announcements and policy discussion items.
- Approval of minutes from the previous meeting.
- Continuing Review Projects:
 - Continuing Review – No Revisions.
 - Continuing Review – With Revisions.
 - Review of Revisions Only.
- Second Review Projects (projects for which approval has been deferred).
- New Projects.
- Other Business and Items for Discussion:
- Correspondence with the CPHS (including adverse event reports).
- Projects that have been completed or withdrawn.
- Terminated or expired projects.
- Continuing education materials.
- Expedited Review Requests Since Last Meeting – including project number, title, principal investigator, and a brief statement summarizing revisions.
- Exemption Requests Since Last Meeting – including project title, principal investigator, and if approved or denied.
- Next Meeting – date and location.
- Contact information for the CPHS.

Pre-Meeting Set-up - CPHS staff set up recording equipment the evening before the meeting. The CPHS Administrator prepares a "Good Morning Memo" which contains the requisite number to attain a quorum, the expected number of members in attendance, announcements, issues for policy discussion, and a list of last-minute materials for projects on the agenda. At each member's seat are: copies of the memo, agenda, draft of the previous meeting's minutes, and any additional project materials, note pad, pencil, and the member's nameplate.

Proceedings

Meetings are conducted in accordance with the Bagley- Keene Open Meeting Act, Robert's Rules of Order, and U.S. Office of Human Research Protection requirements.

Meetings are open to the public and recorded on cassette tape.

Researchers may arrange to appear before the CPHS via telephone by contacting the CPHS Administrator at least 3 days before the meeting.

The Chair calls the meeting to order (the Vice-chair assumes this responsibility in absence of the chair) and a quorum count is taken.

Researchers are requested to provide the CPHS with a brief verbal overview of each new proposal, including a brief summary of project background, objectives, a description of human subjects, how they will participate, and any potential risks and steps taken to minimize those risks.

Primary reviewers discuss concerns they have about each project, followed by a discussion of concerns by other CPHS members.

The primary reviewer, or other committee member, presents a motion for action on the proposal based on the five (5) decision options listed in X.A.5 above. All motions for approval or approval deferred pending minor revisions must designate a time interval, based on project risk, for approval, not to exceed one (1) year. A motion must be seconded by another CPHS member before it can be called to a vote.

The motion for approval will include a designated time period for renewal not to exceed one (1) year.

Approval of a motion requires "yes" votes by a majority of CPHS members present, excluding the Chair. The Chair may cast a tie-breaking vote or may vote if his/her presence is necessary for the meeting to have a quorum.

Notification of Principal Investigators - Principal investigators will be informed of CPHS decisions at the meeting and in writing within 15 working days after each meeting. The written notification will include:

Date of Review.

- CPHS Project Number.
- Project Title.
- Name of Principal Investigator.

- Data base(s) involved in research. This is applicable only to approval letters and should specify the data base name, version, subsets of variables (if applicable), and time period(s), e.g., 1999-2000.
- Type of Review (e.g., full committee or expedited, new or continuing).
- CPHS action (e.g., approved, tabled, etc.).
- Revisions requested by CPHS, if applicable.
- Statement that the project does or does not satisfy additional requirements for research involving vulnerable populations, if applicable.
- Statement that the project does or does not satisfy requirements for a waiver (or alteration) of patient authorization for release of protected health information under HIPAA, if applicable.
- Expiration date of approval.
- Instructions for future review (e.g., project must be submitted for expedited review or full committee review of revisions and continuing review).
- Important investigator responsibilities (e.g., investigators must submit proposed revisions for review and approval prior to implementation even if approved by another institutional review board, and adverse events must be reported within 48 hours).

Notification of Departments - Researchers are expected to forward copies of CPHS approval notifications to departments requesting such copies. CPHS does not routinely forward copies of notifications to department staff unless they are serving as principal investigators for the project.

Meeting Minutes - All pages of the minutes should be numbered, include a label (e.g., "CPHS Minutes" in page header), and date of the meeting. One hard copy of the approved set of minutes is kept in a filing cabinet. Electronic versions of the approved minutes are kept on the CHPDAC shared drive. Copies of relevant sections of the approved minutes are placed in each project's file. Copies of approved minutes may be requested from CPHS staff. Copies of relevant minutes are sent to institutional review boards or institutions that have an AAIP with CPHS. Minutes shall document the following:

- Date and location of the meeting, including the time the meeting was called to order and by whom.
- Satisfaction of quorum requirements (number of members needed, number of members present, and presence of at least one non-scientific member).

- Identity of: members present, members absent, members present with special population expertise (e.g., prison advocate or staff), and CPHS consultants.
- Summary of announcements and policy discussion.
- Summary of discussion and vote count to approve minutes from previous meeting.

Individual project information:

- Project title.
- Project number.
- Principal investigator.
- Primary reviewer.
- Representatives present to discuss the project, if different from meeting attendance.
- Summary of the project and/or proposed revisions.
- Summary of issues discussed by the CPHS.
- Motions and CPHS decision, including votes in favor, votes opposed, abstentions, and members absent at the time of vote (e.g., Total= 15; In Favor-14, Opposed-1, Abstained-0), as well as reasons for minority opinions.
- Degree of risk.
- Review interval.
- Compliance with requirements for waiver of informed consent, if applicable.
- Compliance with special protections for vulnerable populations, if applicable.
- Compliance with requirements for waiver of patient authorization under HIPAA, if applicable.

Summary of projects approved by expedited review since last meeting including:

- Project title.
- Project number.
- Principal investigator.
- Subcommittee members and their votes.
- Justification for expedited review (e.g., data-only, or minor revisions in currently approved research, continuing review of inactive or minimal risk research).
- Brief summary of the project if new or brief description of proposed revisions for a currently approved project.

Projects exempted from CPHS review since last meeting, including:

- Project title.
- Principal investigator/project contact.
- Reason for exemption.

Discussion of Adverse Event Reports, including:

- Project title.
- Project number.
- Principal investigator(s).
- Date(s) of adverse events.

- Description of adverse events.
- Acknowledgement of receipt of adverse event report.
- Summary of CPHS recommendations and actions, if applicable.

Summary of other items discussed.

Time of adjournment.

Distribution of Materials to Members

CPHS Staff Review - CPHS staff reviews all materials for completeness prior to distribution. Staff will contact the principal investigator or the primary contact person for a project when additional or revised materials are needed.

Full-Committee Meetings - CPHS members receive new project materials for full-committee meetings 12 calendar days in advance of the meeting. CPHS staff collates materials according to their position on the agenda. Boxes are prepared and mailed by 2-day service (14 days in advance of the meeting). Members receive the following materials for each project: cover letter/form, human subjects research protocol (basic), translations, curriculum vitae of all investigators and translators, informed consent and assent forms, study instruments, letters of support, approval letters from other institutional review boards, grant proposal (primary reviewer only), CPHS review checklists (primary reviewer only).

CPHS members receive all other materials for full-committee meetings seven (7) calendar days in advance of the meeting.

CPHS staff collates materials according to their position on the agenda. Boxes are prepared and mailed by two (2) day service (9 days in advance of the meeting). Members receive the following materials: memo from CPHS administrator (expected number who will attend, special notes about specific projects, index of contents in the box), order-out lunch menu, complete agenda, draft of minutes from previous meeting, continuing review materials (with and without revisions), revisions for currently approved projects (all members receive copies of materials with revisions highlighted, only the primary reviewer receives a clean copy of documents with revisions incorporated), "second" review materials for projects previously submitted as a new project, but not approved at initial review, new projects, completed projects (the primary reviewer and Chair receive the final Continuing Review form, only the primary reviewer receives final reports and publications--these materials are available to any other member upon request), copies of correspondence and other business documents for discussion, recent publications, and other review materials.

In some cases, a third, or "supplemental," mailing is required when investigators fail to submit all project materials by the deadline or investigators revise previously submitted materials to address CPHS members' concerns. Members must receive these materials no less than seven (7) days prior to the meeting. Materials received by CPHS staff during the week of the meeting will be distributed at the meeting.

Expedited Review - Materials for expedited review are mailed within five (5) working days of receipt by CPHS staff to the Chair and/or designated CPHS member(s).

Exemption Requests - Materials submitted with exemption requests are mailed to the Chair with a recommendation for or against exemption by the Administrator.

Other Materials - The CPHS Administrator periodically sends out continuing education materials or materials relevant to the CPHS.

Project Approval

CPHS approval is based upon the seven (7) criteria delineated in 45 CFR 46.111, as listed below. For projects involving vulnerable populations, the CPHS takes into consideration special protections as listed in Subparts B, C, and D. Checklists are used by the primary reviewer when conducting review of projects involving vulnerable populations and become part of the official project file.

Risks to subjects are minimized:

- By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CPHS will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The CPHS will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Selection of subjects is equitable. In making this assessment the CPHS will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

When appropriate, the research plan will make adequate provision for monitoring the data collected to ensure the safety of subjects.

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Continuing Review

The CPHS is responsible for ongoing review of research projects and reviews all continuing projects at least yearly or more frequently as deemed necessary by the CPHS based upon

potential subject risk and other factors. If a project is within five (5) months of its renewal date when applying for approval of a change in the project, the principal investigator(s) may elect to submit a complete continuing review package. The renewal date for the project, if approved, will then be adjusted accordingly (unless otherwise specified it will become one (1) year from the date of the new approval). As part of continuing reviews the CPHS may take the actions designated in X.A.5 above. Continuing review will focus on the following issues:

Have adverse events been addressed appropriately by the researchers and do these events increase risk for subjects?

Do interim findings justify continuation of the research project?

Has recent literature been appropriately reviewed by the researcher and does it support continuation of the research project?

Are currently approved informed consent documents still accurate and complete?

Are current approved waived or alteration of informed consent still justified?

Expedited Review

The subcommittee can communicate with the principal investigator regarding needed revisions, but cannot take any actions other than approval or referral of the project to the full committee. Expedited review decisions must be made by the subcommittee within two (2) weeks of receipt of materials.

New Projects - The CPHS may carry out an expedited review process for new proposals that present no more than minimal risk for human subjects and use data or materials data that have already been collected for other purposes and which will not involve any contact with human subjects. Projects for which the full committee has taken the action "approval deferred pending specific minor changes" also may be approved by expedited review provided the changes have previously been discussed by the full CPHS. Projects subject to U.S. Food and Drug Administration regulation are not eligible for expedited review. For new projects, expedited review must be conducted by a subcommittee composed of the Chair or Vice-chair and one other member. Approval of new projects by expedited review requires unanimous "yes" votes by both subcommittee members. If the subcommittee does not approve the project, it must be referred for review by the full CPHS.

Previously Approved Projects - The CPHS may carry out expedited review of minor changes in a previously approved research project during the period for which approval is authorized. Examples of minor revisions include:

- Wording changes that do not substantially alter the meaning of project protocols, informed consent documents, or project materials.
- Changes in the research period.
- Changes in subject number or subject selection procedures.
- Changes are data base years or variables if the changes do not present additional risks of

loss of confidentiality.

Continuing Review - Continuing review of a project may be conducted on an expedited basis by the primary reviewer or other CPHS member designated by the Chair if the project has previously been deemed minimal risk by the full CPHS and no additional risks have been identified, or:

- The research is permanently closed to the enrollment of new subjects and all subjects have completed all research- related interventions and the research remains active only for long-term follow-up, or
- no subjects have been enrolled and no additional risks have been identified, or
- remaining research activities are limited to data analysis.

Exempt Research

The CPHS Administrator, with approval of the Chair, can grant an exemption from CPHS review if any of the following criteria delineated in 45 CFR 46.101 are satisfied:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- 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.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2 above, if:

- The human subjects are elected or appointed public officials or candidates for public office; or
- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Research involving the collection or study of existing data, documents, records, pathological specimen, 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.

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; or
- possible changes in methods or levels of payment for benefits or services under those programs.

Taste and food quality evaluation and consumer acceptance studies,

- if wholesome foods without additives are consumed, or
- 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Distinguishing Public Health Practice from Research

CPHS recognizes that public health authorities must be free to conduct routine disease surveillance and perform interventions to protect the health of the public without prior institutional review board approval. The CPHS considers the following factors to be important in determining that an activity qualifies as public health practice instead of research:

The activity is carried out under the direct supervision of a governmental public health agency.

The activity addresses an important health issue for the population under the authority of the public health agency and is carried out for the benefit of that population.

The activity constitutes accepted public health or medical practice and is not designed to test an experimental hypothesis, drug, or device.

The public health authority has pre-existing legal authority to receive any confidential, identifiable information to be used in the activity.

Additional Considerations:

- Surveillance or study of highly personal behaviors, particularly with vulnerable populations, in general,

- should be considered research, and thus requires institutional review board approval.
- Publication of information obtained from public health practice or surveillance does not, in itself, indicate that the activity is research.
- Identifiable data obtained from public health surveillance activities may not be shared or used for research purposes without institutional review board approval.

HIPAA Waiver or Alteration of Patient Authorization for Release of Protected Health Information

Under the Health Insurance Portability and Accountability Act (HIPAA), CPHS is authorized to approve waivers or alterations of patient authorizations for release of protected health information. Such approvals may be granted by either full committee review or by expedited review by the CPHS Chair or a member appointed by the Chair. Approvals for HIPAA waivers must be renewed at the time of the next continuing project periodic review for compliance with the Common Rule. Researchers must apply (both for initial and renewal approvals) by submitting a separate letter to the CPHS Administrator that provides a description of the protected health information and the covered entity for which a waiver or alteration of authorization is required. Also, the principal investigator must address the following issues in depth (A substantive discussion must be provided and simple “Yes/No” statements will be considered inadequate):

Does the use or disclosure of the protected health information involve no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements?

An adequate plan to protect the identifiers from improper use and disclosure;

- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA regulations.
- Could the research not practicably be conducted without the waiver or alteration?
- Could the research not practicably be conducted without access to and use of the protected health information?

Death Data Files

Under Section 102231 of the Health and Safety Code, any release of death data files containing the social security numbers and/or mothers’ maiden names of deceased persons to researchers expressing valid scientific interest requires the review and approval of the CPHS. Researchers must submit an application form and protocol (using a format abridged from that used for Common Rule review) to the Center for Health Statistics, Department of Health Services. The protocol is forwarded to the CPHS for review. Review may be conducted by the full committee or expedited review by the Chair and one committee member. Decisions to disapprove or approve protocols

can be made by expedited review if both reviewers are in agreement. If both reviewers do not agree, the protocol must be referred to the full committee for review. Approvals do not need to be renewed and are in effect for the life of the project. If the project design is changed (including requests for data from different years), a request for changes to a continuing project must be submitted to CPHS.

Appeals

Principal investigators may request appeal of decision made by the CPHS Administrator by contacting the CPHS Chair. Decisions made by the CPHS Chair or individual members in the course of expedited review can be appealed to the full committee. Principal investigators may request an appeal to the full committee by contacting the CPHS Administrator. Decisions of the full committee cannot be altered by the CHHSA, other institutional review boards, or any other authority.

Records Management and Retention

Project Files - All protocols and other project documents submitted for formal CPHS review are maintained in project files in reverse chronological order. Each page of project documents reflects the date/version of the document. All project files will be retained by the CPHS for a minimum of 10 years following completion or termination of a project. Project records will be archived two years after completion or termination of a project.

Correspondence - All correspondence to and from the CPHS regarding a specific project is placed in that project's file. CPHS staff date-stamps all correspondence received by the CPHS. CPHS staff place copies of electronic and written correspondence between CPHS members, staff, and researchers in the project file.

CPHS members are responsible for forwarding or sending copies of all correspondence to the CPHS Administrator. Formal communications from the CPHS to investigators are sent on CPHS letterhead, properly dated, and identifying the project title and number. Correspondences not received from or addressed to a principal investigator are maintained in a designated correspondence file (e.g., records of all correspondence with OHRP are maintained in reverse chronological order in a file).

Correspondence will be retained for 10 years.

Membership Records - CPHS membership records are maintained by CPHS staff in accordance with 45 CFR 46.115.

- **Curriculum Vitae** - Each member is required to provide updated curriculum vitae every 3 years.
- **Abbreviated CPHS Roster** - This roster contains a complete listing of all CPHS members and staff including names, credentials, and email addresses. This roster is distributed to investigators.
- **Summary of Membership Qualifications** - This list summarizes members' experience and professional backgrounds, including length of service on the CPHS, institutional affiliation, and special representative capacity (e.g., prisoner advocate). This list is included in the

Federalwide Assurance.

- Membership Roster - This roster contains a complete listing of all CPHS members and includes names and credentials, occupations, place of employment, address, phone number, fax number, and email address. This roster is updated regularly to reflect changes in membership or contact information. This roster is for internal CPHS use and is not distributed to investigators.

Educational Outreach and Training for Researchers

The CPHS Chair and staff will provide information and training to investigators involved in human subjects research to assure that they are familiar with the statutory requirements, ethical guidelines, and CPHS policies and procedures for conducting human subjects research.

Internet links for relevant guidelines and regulations will be posted on the CPHS web site.

An investigator's manual describing the process for submission of research proposals to the CPHS will be posted on the CPHS web site.

The CPHS Administrator and Chair will periodically give presentations to each CHHSA department.

All researchers and project managers/coordinators will be on the CPHS mailing list and will receive updates about new CPHS policies and procedures and new statutory requirements for conducting human subjects research.

Adverse Events

Investigators are required to send written or electronic notification of an adverse event within 48 hours of the event to the CPHS Administrator. This report is shared with CPHS members and is placed in the designated adverse event section of the project file. The CPHS Chair or Vice Chair and the primary reviewer of the project are responsible for determining whether immediate action needs to be taken regarding the adverse event(s). The Chair can direct the Administrator to issue a notice to the principal investigator suspending the project approval and/or take other actions deemed necessary for subject safety until the project can be reviewed by the full committee at the next meeting. After review of adverse event reports, the CPHS can order termination or revision of a project to protect the welfare and safety of subjects. The CPHS reports all serious events to the Secretary of the California Health and Human Services Agency, the U.S. Office of Human Research Protection, the funding agency (whether federal, state, or private), and the responsible official of the project.