CPHS Policies and Procedures

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Institutional Authority

The California Health and Human Services Agency (CalHHS) established the Committee for the Protection of Human Subjects (CPHS), an Institutional Review Board (IRB), in July 1976 to review research projects involving human subjects under the federal Common Rule. CPHS is bound by the terms of the Federalwide Assurance (FWA) 00000681 signed with the U.S. Department of Health and Human Services, Office for Human Research Protections. CPHS is the only IRB empowered by CalHHS. In 2006, changes to Civil Code section 1798.24(t) established requirements for CPHS to use in reviewing the release of identifiable state data by any state department for research. CPHS adopts these policies and procedures to implement its duties under both the FWA and Civil Code section 1798.24(t).

Purpose of the CPHS

CPHS has two functions: (1) to review all releases of confidential state data for research projects by any state department and (2) to review research involving human subject contact that is conducted or funded by CalHHS departmental staff or its departments or involves human subjects under the custodial protection of CalHHS or its departments. CPHS is required by law to review research requests for state data under the criteria listed in Civil Code section 1798.24(t). CPHS conducts reviews of research involving human subject contact in compliance with Title 45, Part 46 of the Code of Federal Regulations (Common Rule).

Additionally, when applicable, CPHS reviews research involving experimental drugs or devices under Title 21, Parts 50 and 56 of the Code of Federal Regulations (FDA Regulations). CPHS, upon request, may review 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

For all research involving human subjects, CPHS is 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.

When a research project involves requests for both state data and participation by human subjects, the CPHS is governed by both the Civil Code criteria and the Belmont Report. For these projects, the Committee must review the request for state data only using the criteria in the Civil Code. The Committee must use the Common Rule criteria and consider the ethical principles of the Belmont report when reviewing the portion of the research that involves human subjects.

Authority of CPHS

Scope of Authority

Jurisdiction

Data Only Projects: CPHS has jurisdiction to review all research projects that involve state data. The scope of CPHS' review is limited to the criteria listed in Civil Code section 1798.24(t).

Human Subjects Projects: CPHS has jurisdiction as an IRB to review research projects conducted by or funded by (regardless of original source) the CalHHS and its 13 component departments (see below) that involve human subject contact. Jurisdiction also includes all research involving subjects for whom the CalHHS or its components have direct responsibility, such as patients in state hospitals. CPHS also has jurisdiction to choose to review projects as an IRB for other public entities, such as a public university, as well as entities that do not have their own IRB, such as a county. CPHS has authority to review projects as an IRB when the CPHS has a contract with another IRB authorizing the review consistent with the federal Common Rule (see Reciprocity with other Institutions below).
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
Department of Health Care Access and Information
Office of Youth and Community Restoration

Combined Human Subjects and Data Projects: CPHS has jurisdiction to review the portion of the project that involves state data only using the Civil Code criteria specified in section 1798.24(t) of the Civil Code and the portion of projects that involve human subject contact using the criteria in the federal Common Rule.

Please click the link below to open the CPHS Review Pathways for an illustration of the CPHS' authority.

CPHS Review Pathways Chart

Definition of Research

As defined in 42 C.F.R. part 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

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

CPHS may engage in formal agreements to serve as the IRB for other institutions in California with current Federalwide Assurances in place. Reciprocity arrangements to enable other IRBs to approve projects for the CPHS are currently in place only with selected federally designated IRBs.

CPHS may delegate reviews of data releases under Civil Code section 1798.24(t) to other institutional review boards, but currently does not have any such delegations in place.

California Health and Human Services Agency (CalHHS) Responsibilities

- The Secretary of CalHHS is the signatory of CalHHS' 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 C.F.R. Part 46 in the Federalwide Assurance to the U.S. Department of Health and Human Services.

- Enforce policies requiring that all research conducted by CalHHS staff, funded by involving state data is a CalHHS department, or involving human subjects under custodial care of CalHHS is reviewed and approved by CPHS, unless otherwise exempted by CPHS.

- Provide sufficient professional staff or consultants to support the activities of CPHS.

- Set expectations among CalHHS appointing authorities that CPHS members who are CalHHS employees will be making a significant time commitment to the CPHS.

- Support measures to educate CPHS members about protections for human subjects.

- Maintain open channels of communication between CPHS members, staff, subjects, Researchers, and other interested parties both within and outside of CalHHS.

- Assure that CalHHS executive and legal staff are available to provide guidance to CPHS, department heads and other officials with responsibility for oversight of research.

- CalHHS 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.

- In compliance with the Federalwide Assurance and the IPA, CalHHS officials may not approve research involving human subjects or release of state data if CPHS has not approved it.

CPHS Members

Selection and Appointment

Members are appointed by and serve at the pleasure of the Secretary of CalHHS. Membership must fulfill the requirements of 42 C.F.R. part 46.107:

- CPHS must have at least five (5) members, with varying backgrounds and fields of expertise.
- Members must be knowledgeable in the areas of research that 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 (1) member whose primary expertise is in scientific areas and at least one (1) member whose primary expertise is in nonscientific areas.
- CPHS must have at least one (1) member not affiliated with CalHHS directly or through an immediate family member.
- CPHS must have at least one member with expertise in data privacy or data security.
- Alternate members may be appointed by the Chair and Vice Chair to attend meetings at the invitation of the Chair to replace members not in attendance or if their expertise (i.e., prisoners) is needed to review a research request. Such alternate members must have previously served as regular members.
- Every effort will be made to ensure that the CPHS has a diverse membership, including the use of inclusive outreach and recruitment efforts conscious of race, gender, age and cultural background.

Nominations for membership may be submitted to the CPHS Administrator by CalHHS department heads, any CalHHS 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 part 46.107, to handle increased workload, or upon request of the CalHHS Secretary, the Chair will forward a prioritized list of candidates, with curriculum vitae and reference list, to the CalHHS 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 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 CalHHS departments.
- Knowledge of data privacy and security

Number and Tenure

CPHS is composed of a maximum of 13 regular members. CPHS members serve for a three (3) year term contingent upon continued fulfillment of the duties and responsibilities designated below. Members may be reappointed for additional three (3) year terms at the discretion of the CalHHS Secretary. Alternate members are appointed by the Chair. Members may resign at any time by submitting written notification to the Administrator.

In the event that a renewal of membership occurs after the three (3) year term expires, the member, Chair, and/or Vice-Chair may continue to serve with full membership until the membership is formally renewed or the Secretary denies the renewal.

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 in advance of the meeting, 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 they have 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. A member shall abstain from voting on a project wherein they have a conflict of interest.

Initial Review

Each member will serve as primary reviewer for at least one (1) new project proposal to be assigned by the Administrator for each meeting , if available. In this capacity, the member will review the proposal and contact the Researcher(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

CPHS staff can review continuing review applications for members if:

- The research is permanently closed to the enrollment of new subjects, all subjects have completed all research- related interventions, and remaining research activities are limited to data analysis; And,

- No new adverse events or data breeches have been identified.

Staff may only review continuing projects for a maximum of three (3) years per each project without review by a CPHS member. If possible, members will be assigned review of projects for which they initially have served as the primary reviewer.

Members and staff are expected to complete expedited review within two (2) weeks of receipt of the project proposal. Members will notify the Administrator at least five (5) days in advance of each CPHS Board meeting regarding continuing renewal projects that require principal investigators' attendance. 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 review project.

Expedited Review of New Projects

Two (2) members will carry out expedited review on appropriate new projects. Members are expected to complete expedited review within two (2) weeks of receipt of the project proposal. In some cases, the reviewer will work in collaboration with the CPHS Chair or Vice Chair to determine if a project needs presentation to the Board. Project approval cannot be denied by expedited review of a subcommittee and requires action by the full committee.

Training and Continuing Education

New members are paired with an experienced member to review project materials for the first meeting. All new members must complete the Human Research Protection Foundational Training online at https://www.hhs.gov/ohrp/education-and-outreach/index.html

Members are provided training on the CPHS online system (IRB Manager) used to review and approve protocols. This training is provided by CPHS staff.

Compensation

Members who are not CalHHS or CalHHS department employees are not compensated for their participation. However, travel and incidental expenses are reimbursed by CDII for participating in CPHS meetings and other related activities as approved by the Administrator.

CPHS Chair

Selection and Appointment

- The Chair is nominated by the CDII Director, voted upon by the Committee, and then submitted for appointment by the Secretary of CalHHS.
- The Chair must be a CalHHS or CalHHS department 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 CalHHS.
- After three (3) years of service, the Chair is eligible for additional three year terms of service as Chair upon reappointment by the CalHHS' Secretary.
- In the event that a reappointment to Chair occurs after the three (3) year term expires, the Chair may continue to serve as Chair with full authority until the appointment is formally reappointed or denied by the Secretary.

Duties and Responsibilities

- Assures that the CPHS operates in accordance with the terms of the FWA (shared responsibility with the Administrator) and informs the CalHHS Secretary regarding problems that inhibit the CPHS from fulfilling its functions.
- Ensures that CPHS operates within its authority and consistent with Civil Code section 1798.24(t).
- Advises the Secretary of CalHHS regarding appointment of new CPHS members.
- Advises Researchers both within and outside CalHHS regarding the purpose and functioning of the CPHS.
- Determines projects that need verification of information from source(s) other than the Researcher, including whether material changes have occurred in a project since the last CPHS review.

- Advises the CPHS Administrator regarding daily functioning of the CPHS.
- With the Vice Chair, assigns project proposals to members for primary review
- Assists the CPHS Administrator in responding to inquiries from Researchers and others both within and outside of CalHHS.
- Proposes policy and procedure changes for the CPHS.
- Represents CPHS at CalHHS meetings, as well as at national meetings. Chairs all meetings of CPHS. If unable to attend, arrange for this to be performed by the Vice Chair.
- Reviews project applications through the expedited review process.
- Collaborator with CPMS members in reviewing applications.
- Provides education to members regarding recent changes in federal policies or regulations (joint responsibility with CPHS Administrator).
- Conducts or arranges educational seminars for Researchers (shared responsibility with the Administrator).
- Reviews requests for not research and exemption determinations projects in collaboration with the CPHS Administrator

CPHS Vice-Chair

Selection and Appointment

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

Tenure

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

Duties and Responsibilities

- Assumes responsibilities of the Chair when the Chair is unavailable.
- Participates in expedited review subcommittees when requested by the Chair.
- Supports the Chair in ensuring that the CPHS complies with its FWA and the Civil Code requirements.

CPHS Administrator

Selection and Appointment

- The CPHS Administrator is selected by the Director of CDII with input from the CPHS Chair and/or Vice Chair or assigned CPHS Board Member. The CalHHS Secretary, as the designated institutional official on the FWA, approves the designation of the Human Protections Administrator on the FWA.

Duties and Responsibilities

- Assures that CPHS operates in accordance with the terms of the FWA and is in compliance with the Civil Code (shared responsibility with the Chair).
- Serves as the primary liaison between CPHS members and the U.S. Office of Human Subject Protection, investigators, and CalHHS officials.
- Prepares Secretary's Action Requests (SARs) for membership nominations, and other actions needing CalHHS Secretary's approval.
- Assists Researchers in the preparation and submission of research applications for CPHS review.

- Reviews research applications prior to distribution to CPHS members and notify Researchers if applications are incomplete.

- Obtains verification of information about projects from sources other than the Researcher at the direction of the Chair.

- Assigns 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 and Vice Chair).

- Provides materials to CPHS members as needed.

- Works with the Contractor to maintain and improve the system to meet CPHS' workflow, tracks protocols and generate reports.

- Organizes logistics for all CPHS meetings.

- Reviews and approves minutes for CPHS meetings.

- Prepares CPHS correspondence to Researchers.

- Reviews requests for exemptions in collaboration with the CPHS Chair and/or Vice Chair

- Supervises the CPHS administrative staff performs the daily operations and supports the continuous functioning of the CPHS.

- Maintains the CPHS website with assistance from the CDII webmaster.

- Conducts or arrange educational seminars for Researchers (shared responsibility with the Chair and/or Vice Chair).

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

- Approves expense reimbursements for CPHS members, in accordance with CalHR Rules, under the supervision of the Director of CDII.

CPHS Operations

Meetings

Schedule - CPHS meets on the first Friday of even-numbered months (February, April, June, August, October, and December) from 8:30 a.m. until the meeting agenda items are completed. 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: 1215 O Street, Sacramento, CA 95814.

Open Meeting Act - Meetings are conducted in compliance with the Bagley-Keene Open Meetings Act. Copies of all materials are distributed to members and discussed at the meeting. These Board materials 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 Open Meetings Act.

Quorum - In compliance with the Bagley-Keene Open Meetings Act. A quorum is defined as in-person attendance by more than 50% of members. At least one of the members attending in-person or remotely must have 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 – 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 project's primary reviewer or a subcommittee.
- Approval deferred pending specified major revisions requiring a subsequent full committee review.
- Tabled pending resolution of significant issues that will require full committee review of the entire project.
- Disapproved.
- No CPHS purview.

- Not Research.
- Exempt.

Preparation and Posting of Agenda - The CPHS Administrator prepares and emails the meeting agenda to the CDII webmaster at least 17 days before the meeting, since the CDII webmaster requires five (5) working days to post the agenda. CPHS staff sends the agenda and all meeting materials to CPHS committee members and to the contracted transcriber at least ten (10) calendar days before the meeting. The agenda will contain the following items in sequence:

- Location, date and time of the meeting.
- Announcements and policy discussion items.
- Continuing education materials.
- Approval of minutes from the previous meeting.
- Projects with Reported Adverse Events and/or Deviations
- Second Review Projects (projects for which review has been tabled).
- New Projects – Full Committee Review Required
- Amendments – Projects with Major Revisions Requiring Full Committee Review
- New Projects – Expedited Review Requested
- Continuing Reviews – Projects Requiring Periodic Expedited Review Only (Including Greater than Minimal Risk)
- Amendments – Projects with Minor Revisions Approved through Expedited Review
- Projects with Request for CPHS to Rely on Another IRB.
- Exemption Requests Since Last Meeting – including project title, Researcher, and if approved or disapproved.
- Final Reports
- Public Comments
- Next Meeting – date and location. Contact information for the CPHS.

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.
- Researchers may arrange to appear before the CPHS remotely by contacting CPHS Administrator at least three (3) working 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 adverse event, new proposal, or amendment 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 eight (8) decision options listed 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.
- Approval of a motion requires "yes" votes by a majority of CPHS members present in-person or remotely, excluding the Chair. A member having made a motion cannot vote against their own motion. The Chair may only cast a vote in order to break a tie or if their presence is necessary to establish a quorum for the meeting. Motions receiving a tie vote do not pass. Members voting "no" are required to express their reason(s) for opposition.

Notification to Researchers

Researchers 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 Researcher.
- Basis of Review (e.g. Common Rule or IPA)

- 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.
- Reason(s) for disapproval, 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 Researcher responsibilities (e.g., Researchers 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 to 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 Researchers 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. Electronic versions of the approved minutes are kept on the 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. 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 the previous meeting.
- Individual project information:
    - Project title
    - Project number
    - Researcher
    - Basis of Review (Common Rule or Civil Code section 1798.24(t))
    - 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, opposed, abstentions, and members absent at the time of vote (e.g., Total= 13; In Favor-12, Opposed-1, Abstained- 0), as well as reasons for abstaining and opposing.
    - 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.

- Discussion of Adverse Event Reports, including:
    - Project title
    - Project number
    - Researcher(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.
- Number of projects approved by expedited review since last meeting.
- Number of projects exempted from CPHS Common Rule review since last meeting.
- Number of other items
- Time of adjournment

Distribution of Meeting Materials to Members

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

CPHS Member Review - CPHS members receive all meeting materials electronically for full committee review at least ten (10) calendar days in advance of the meeting. Members will also receive access to these projects in IRBManager.

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

Project Approval

Projects Involving State Data

CPHS approval is based on the criteria in Civil Code section 1798.24(t), as listed below. CPHS is limited to these criteria unless the project involves participation by human subjects.

1. The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

2. The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information.

3. The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project.

4. CPHS determines whether the requested personal information is needed to conduct the research.

5. CPHS permits access to personal information only if it is needed for the research project.

6. CPHS permits access only to the minimum necessary personal information needed for the research project.

7. CPHS may require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

8. If feasible, and if cost, time, and technical expertise permit, CPHS may require the department whose data is being released to conduct a portion of the data processing for the researcher to minimize the release of personal information.

Projects Involving Human Subject Contact

CPHS approval is based upon the seven (7) criteria delineated in 45 C.F.R. part 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.

1. 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.

2. 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.

3. Selection of subjects is equitable. In making this assessment CPHS will consider 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.

4. 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 C.F.R. part 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 C.F.R. part 46.117.

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

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

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

CPHS is authorized to approve waivers or alterations of patient authorizations for release of protected health information consistent with HIPAA. 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. CPHS will not consider such waivers if already granted by another IRB.

Expedited Review

The subcommittee can communicate with the Researcher regarding needed revisions to the application. The subcommittee cannot take any actions other than approval or referral of the project to the full committee. However, in the case where the subcommittee believes the project is Not Research, No Purview, or Exempt, the project must be referred to the Chair or Vice Chair. Expedited review decisions will be made by the subcommittee within two weeks of receipt of complete protocol materials.

New Projects

CPHS may provide 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 by the primary reviewer or a subcommittee 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.

Approval of new projects by expedited review requires approval by both subcommittee members. If the subcommittee does not approve the project, it must be referred for review by the full committee.

Previously Approved Projects

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 but not limited to:

- 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

CPHS staff can review continuing review applications if:

- The research is permanently closed to the enrollment of new subjects and all subjects have completed all research-related interventions and remaining research activities are limited to data analysis; And

- New adverse events or date breeches have not been identified.

CPHS Staff cannot perform continuing reviews for any project for more than three years in a row without referring the continuing review to the CPHS member serving as primary reviewer.

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 C.F.R. part 46.101 are satisfied:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (Note: this exemption only applies to research involving children when the investigator(s) do not participate in the educational tests or the observation of public behavior.

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required. (Note: does not apply to research involving children)

(3) Research involving benign behavioral interventions in conjunction with the collection of

information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Please note that this exemption does not apply to research involving children.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 C.F.R. Parts 160 and 164, Subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 C.F.R. part 164.501 or for "public health activities and purposes" as described under 45 C.F.R. part 164.512(b); or
- The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section

208(b) of the E-Government Act of 2002, 44 U.S.C. section 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. section 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. section 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) 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. 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.

Adverse Events

Investigators are required to complete and submit an Adverse Event Report via IRBManager within 48 hours of the event. 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 Researcher 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 CalHHS, the U.S. Office of Human Research Protection, the funding agency (whether federal, state, or private), and the responsible official of the project.

Appeals

Researchers 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. Researchers may request an appeal to the full committee by contacting the CPHS Administrator. Decisions of the full committee cannot be altered by the CalHHS or other institutional review boards.

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 CPHS consistent with CDII's retention policy and state requirements.

Correspondence - All correspondence to and from CPHS regarding a specific project is placed in that project's file in IRB Manager.

Membership Records - CPHS membership records are maintained by CPHS staff in accordance with 45 C.F.R. part 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.
- **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 FWA.

- **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

The CPHS Chair and staff may provide information to Researchers 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 research guidelines and regulations will be posted on the CPHS web site.

- Instructions for Researchers ("CPHS Basics" and "IRBManager User Manual") describing the process for submission of research proposals to the CPHS will be posted on the CPHS website.