

**California Health and Human Services Agency
Committee for the Protection of Human Subjects (CPHS)**

CPHS staff only	
Date Received:	_____
Date to Review:	_____
Due Date:	_____
Final Approval:	_____

CONTINUING PERIODIC REVIEW FORM—HUMAN SUBJECTS CONTACT

PROJECT NO.: _____

PROJECT TITLE: _____

PI Name (please print): _____

PI's Phone #: _____

E-mail: _____

Address: _____

Other Contact Person Name (if applicable): _____

Phone #: _____

E-mail: _____

Other Contact Title: _____

Please respond to the following issues and questions:

1. Status of project:

- Continuing:** Please attach any findings to date and include a copy of all publications.
- Completed:** Please attach any findings to date and include a copy of all publications.
- Withdrawn:** Please provide in the cover letter an explanation of why the project is being withdrawn.
- HIPAA waiver or alteration of authorization requested:**

Please include in the cover letter a statement as to whether there have been any changes in data security practices or other factors relevant to the continuing of the waiver.

2. List the formal names of any California Health and Human Services Agency (CHHSA) databases, such as the Cancer Registry, or specimens, such as blood spots, to be used in this project.

Department	Name of Database(s)/Specimen(s)
Dept. of Public Health	_____
Dept. of Health Care Services	_____
Office of Statewide Health Planning and Development	_____
Dept. of Mental Health	_____
Dept. of Developmental Services	_____
Dept. of Social Services	_____
*	_____
*	_____

3. Check the box(es) which indicates the nature of each CHHSA department's involvement – e.g., Funding (pass through or source of funding), Principal Investigator (PI), research staff involved (staff), or supplying human subjects (note that **only** subjects for which the State has direct responsibility, e.g., mental hospital patients should be included.). *Specify any other CHHSA departments involved.

Department	Funding	PI	Staff	Subjects
DPH	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DHCS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OSHPD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DMH	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DSS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
* _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Specify other department(s) involved.

4. Indicate the amount of funding project receives from each source listed below.

Federal \$ _____ State \$ _____ Foundation \$ _____ Other \$ _____
Total \$ _____

5. Has the involvement of human subjects permanently ended? This includes contact, enrollment, and interventions?

Yes No

6. Have any complaints, verbal or written, been received from study participants?

Yes No

(If "Yes," attach a copy and description of details.)

7. Have there been any adverse events?

Yes No

(If "Yes," attach a **detailed** explanation.)

8. Have there been any breaches of data security?

Yes No

(If "Yes," attach a *detailed* explanation.)

9. Have there been any difficulties or unanticipated problems experienced during the research?

Yes No

(If "Yes," attach a *detailed* explanation.)

10. Are you requesting any changes to your approved protocol, including use of additional years of data?

Yes No

(If "Yes", please specify and justify revisions and address whether revisions change subjects' risk level in the box below. Please attach copies of old protocol with tracked changes and clean copies of new protocol with original signatures from Principal Investigator (PI) and Responsible Official (RO).)

11. Are you proposing any new documents or changes to other project documents (e.g., consent forms, survey instruments, translations)?

Yes No

(If "Yes," please specify and justify revisions and address whether revisions change subjects' risk level in the box below. Attach old materials with tracked changes and clean copies of new materials and ensure protocol reflects changes, as appropriate.)

12. Are you requesting a change in PI or RO?

Yes No

(If "Yes", please specify the previous PI or RO and the new PI or RO in the box below. If a new PI is being added, address conflict of interest questions, including description of financial or other relationships that could be perceived as affecting objective research and the interpretation and publication of findings. Submit new PI's curriculum vitae. See Instructions for Researchers, Appendix I, #12 for financial relationship examples.)

13. Date subject enrollment began: _____ Number of proposed subjects: _____

A. Total number of subjects enrolled since project began (active and inactive): _____

B. Number of subjects currently enrolled in project: _____

C. Number of subjects offered enrollment in past year: _____

D. Number of subjects who declined enrollment in the past year: _____

E. Total number of subjects withdrawn since project began (attach reasons): _____

F. Number of subjects expected to enroll in coming year: _____

G. Expected total number in project: _____

H. Expected completion date of project: _____

14. HIPAA - include any changes in data security practices or other factors that may be relevant to the waiver for HIPAA waiver of authorization, if applicable?

Yes No NA

(If "Yes", explain in the box below)

15. Project Chronology - provide a dated sequence of significant events in the project's history, including all changes reviewed by CPHS in the box below.

16. Protocol Summary - provide a short description of the basic elements of the study as currently conducted in the box below.

17. Interim Findings - provide a summary statement of interim findings and other relevant information in the box below.

18. Literature Review – provide a summary of relevant scientific literature in the box below.

19. Attach any reports or publications related to this research.

Signature of P.I.: _____

Date: _____

Project #: _____

Name of PI (Please print or type): _____

CPHS Use Only

STAFF: Project eligible for Expedited Review due to:

- Completed** or **Withdrawn**
- CPHS determined minimal risk
- All human intervention-related research has permanently ended
- No subjects enrolled & no added risks have been identified

- Yes No Revisions
- Yes No **HIPAA** approval or renewal required

Circle Reviewers:

Dickey Lowe Dinis Galbraith Harris Kirkish Mihordin Murphy Ruiz Snipes Ward Staff

REVIEWER:

- Yes No N/A Have adverse events (AE) been appropriately addressed by researcher and, if any AE, these AEs do not increase risk for subjects?
- Yes No N/A Is the currently approved informed consent forms still accurate & complete?
- Yes No N/A Is currently approved waiver or alteration of informed consent still justified?
- Yes No N/A Do interim findings justify continuation of the research?
- Yes No N/A Is recent literature adequately reviewed & support continued research?

If revisions:

- Yes No These revisions **are** minor
 - Yes No These revisions **do not** increase risk to subjects
 - Yes No. These revisions are **approved**
- If No, is project referred to Full Committee? Yes No

Explain:

- Approved for **Common Rule** **Common Rule** deferred, pending minor revisions (Comments)
- Approved for one year Approved for less than one year, specify; _____

HIPAA:

- Approved HIPAA waiver Does not affect HIPAA (if applicable)
- HIPAA waiver deferred pending revisions

Translations:

- Approved translations

Completed or Withdrawn Project

- Yes No Is the plan for data destruction or return appropriate?
- Yes No Has PI provided sufficient information re: publications/reports?
- Yes No Are the reasons for withdrawal appropriate?
- Approved Not approved, explain:

Comments:

- If revisions required:** Member must confirm revisions Staff may confirm revisions
- CPHS staff approves revisions (initial and date):

CPHS Member or Staff Signature _____ **Date** _____

Please fax/scan the signed form to: CPHS Administrator Phone: 916-326-3660 Fax:916-322-2512