

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: _____

Revisions Only Request Form

PROJECT NO.: _____
PROJECT TITLE: _____

PI Name _____
PI's Phone #: _____
E-mail: _____
Mailing Address: _____

Contact Person Name (if applicable): _____
Phone #: _____
E-mail: _____
Other Contact's Title: _____

1. 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)).

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

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.)

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

Yes No

(If "Yes," please specify the previous and the new PI and/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 and submit new PI's curriculum vitae. See Instructions for Researchers, Appendix I, #12 for financial relationship examples.)

Signature of P.I.: _____

Date: _____

Project #: _____

Name of PI (Please print or type): _____

CPHS Use Only

STAFF:

Circle Reviewers:

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

Project eligible for Expedited Review due to:

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

- Yes No **SB 13** revisions review required

HIPAA:

- HIPAA waiver renewal requested
- HIPAA waiver requested

REVIEWER:

- 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 (specify):
- Approved for one year Approved for less than one year, specify: _____

- Approved for **SB 13**, if required **SB 13** approval deferred pending minor revisions (Comments)

HIPAA

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

Translations:

- Approved translations

Comments:

- If revisions required:** Member confirms revisions CPHS staff may confirm revisions
- CPHS staff approves revisions (initial and data):

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

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