

CPHS News: Ten-Year Approval Periods for Most Minimal Risk Research!

To: All Human Subjects Researchers at UC Berkeley

From: CPHS and OPHS

Re: Cessation of Continuing Reviews for Most Minimal Risk Research

*Executive Summary: The three-year approval period for qualifying minimal risk, non-federally funded or regulated research, established by CPHS/OPHS in June 2013, was deemed successful. **The approval period for qualifying protocols has now been extended to a 10-year duration.** (Practically speaking, this represents an indefinite approval period similar to Exempt level determinations). Investigators must still amend these protocols for any changes in personnel, funding, data collection, etc., and report any unanticipated problems, serious adverse events, and/or protocol deviations per usual.*

In the spirit of reducing administrative burden on investigators by utilizing the flexibility inherent in the regulations governing human subjects research (45 CFR 46), the CPHS Executive Committee has approved a proposal to cease ALL continuing reviews of qualifying minimal-risk protocols (unless the study continues beyond 10 years). This new open-ended approval process became **effective as of April 15, 2016**, upon vote at the CPHS Executive Committee meeting.

Protocols currently pending with CPHS/OPHS that qualify for this new extended approval period will be granted such approvals at the time of processing.

Please carefully read the list below that identifies what types of projects do NOT qualify for the open-ended (10-year) approval period. Note: It is still the PI's responsibility to submit protocols for continuing review in a timely manner if such review is necessary.

The following DO NOT qualify for a 10-year approval period:

1. Federally funded research, or research with funding from non-Public Health Service (PHS) agencies (e.g., foundations) that adhere to federal regulations in their award contracts. (For a current list of these agencies, see http://sites.nationalacademies.org/PGA/fdp/PGA_070596).
2. Research projects that CPHS determines are "greater than minimal risk" studies.
3. Research involving federal personnel or the Department of Veterans Affairs.
4. Research involving procedures, devices, or drugs subject to FDA oversight.
5. Research involving sponsor or other contractual restrictions that require annual review.

6. Research involving a conflict of interest (COI) for any study personnel.

7. Research involving a Certificate of Confidentiality.

Other Limitations:

This 10-year approval period will not be available to any collaborating institution or investigator relying on UCB's review *unless* verified in writing as acceptable by the other IRB. (An email from the relying IRB is sufficient for this purpose). This 10-year approval period also does not apply to any industry-sponsored research or other individuals, entities, or institutions to which UCB charges a fee for IRB review.

Amendments:

Investigators are expected to modify and/or update their protocols through an amendment or through the continuing review process if federal funding is being added to support the study. This must be done in advance of implementing any change planned to the protocol (e.g., in procedures, design, personnel, subjects, sites, funding, recruitment or data collection materials, consent materials, etc.). It is the investigator's responsibility to ensure that the protocol at all times accurately reflects the research study.

Reporting Requirements:

If there is an unanticipated problem involving risks to subjects or a serious adverse event, it must be reported as usual. Likewise, any deviation from the approved protocol must also be reported.

Monitoring:

CPHS/OPHS reserves the right at any time to monitor research processes and/or audit research records (e.g., consent forms) to ensure compliance with the new 10-year approval period conditions.