



Department of Public Health Institutional Review Board
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Los Angeles, CA 90012
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<http://publichealth.lacounty.gov/irb/>

Checklist of Items You Will Need to Submit an Amendment Application

REMEMBER: Any changes to project activities cannot be implemented until an official approval letter from the IRB has been obtained.

- ***For projects originating in DPH, involving DPH staff/clients, or funded by DPH:*** if you are adding a survey or questionnaire to your project as part of the amendment application, you will need to obtain documentation that surveys have undergone review by the Office of Health Assessment Rapid Assessment, Evaluation and Training unit (RATE) is required. RATE review should be obtained prior to submitting an amendment application to the IRB. To comply with the RATE review requirement, please submit your revised protocol and survey(s) to irb@ph.lacounty.gov. IRB staff will forward the documents to RATE. You will receive an email response from RATE with their feedback. Please upload clean copies of your revised survey(s) and protocol to your amendment application in addition to a PDF of the email from RATE confirming that your documents have been reviewed.
 - ***If you are adding a DHS site, a DHS dataset, or DHS patients/staff to your project:*** your amendment application may need to undergo review by DHS' Research Oversight Board (ROB). Please submit all amendment materials, including a revised protocol, to irb@ph.lacounty.gov. IRB staff will work with the ROB liaison to determine whether ROB review is needed. If ROB review is required, no further action is required on your part and you will receive the result of their review via email - include a PDF of the email (including the assigned category number) with your amendment application in IRBManager. If the ROB decides that their review is not required, please include a PDF of the email confirmation with your amendment application.
- A summary of all changes that are being requested as part of the amendment application (500 word limit).
 - "Tracked changes" and "clean" (i.e., without any internal comments) versions of your protocol. If your protocol does not require any modification from the previously approved version, you may upload the "clean" version of the previously approved protocol in both spaces.
 - All documents (including consent forms, recruitment materials, surveys, interview scripts, etc.) that are being modified as part of the amendment must be included with your amendment application. If you are

modifying a document that was previously approved by the IRB, you must provide both “tracked changes” and “clean” versions so that IRB staff are able to compare the differences. If you are adding a new document that was not previously approved, you only need to provide a “clean” version of that document. Include any translated versions of study documents with your application, as applicable.*

- If your amendment adds the collection or use of Protected Health Information (PHI), you will need to include a HIPAA Authorization form with your amendment application or a strong justification for a waiver. Please use the HIPAA authorization form template provided on the IRB [website](#).
- If your proposed modifications require the use of a new (i.e., not previously approved) software application to access, collect or analyze data, OR you will be using a previously approved software for a purpose other than previously approved, you will need to include documentation of PHIS IT approval with your amendment application. After answering a set of software-related questions on the amendment application, a ticket will be automatically created with PHIS to request approval for each new software used as part of your project. Project teams must work with PHIS to create a secure folder that is only accessible to staff working with the data. PHIS will send an email with their approval to the person who submitted the application. Please upload a PDF of the confirmation email to your amendment application. **Allow up to 2 weeks to obtain PHIS approval.**
- If you are adding any new personnel to your project, you will be required to provide the following for each new personnel: professional qualifications such as a resume/CV, current Human Subjects Protection Training certification, and current HIPAA Training certification. Please refer to the [Training](#) page on the IRB website for more information about training requirements.
- If your amendment includes a change in funding amount or source, please include a revised budget with your application.
- If you are requesting to add a DPH laboratory to your project activities, you will need to include the Laboratory Review Form with your application. Please refer to our [website](#) for a copy of the form.
- The Principal Investigator(PI)/project lead, Co-PI (if applicable), Division Chief/Program Director, and DPH/DHS liaison (if applicable) will need to provide their signature throughout the amendment process similar to the process for submitting a new IRB application. Please ensure they check their email account (including spam/junk folders) for any notifications and provide their signatures promptly to avoid any delays in the review process.

*** Regarding translation of study materials**

If a document such as an informed consent form, survey or interview script must first be approved in English

before translations can take place, please upload a document explaining this to your application (in the space provided for translated files). When the translated documents are available, email the files to irb@ph.lacounty.gov (and reference the IRB# and title of the study in the email subject).

NOTE: The DPH Center for Health Equity's Language Justice Unit is now offering written translation services available to DPH staff involved with DPH-related projects. If you would like more information about the languages that are offered and the process for submitting written translation requests, please visit the following page: <http://intranet.ph.lacounty.gov/ph/hitsystem.htm>