COUNTY OF LOS ANGELES
**Public Health**

Department of Public Health Institutional Review Board
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http://publichealth.lacounty.gov/irb/

# Checklist of Items You Will Need to Submit an Amendment Application

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

**Before you submit an amendment application**

- *For projects originating in DPH, involving DPH staff/clients, or funded by DPH:*
  If you are adding a survey to your project or making changes to a previously approved survey as part of the amendment application, the new and/or amended survey(s) will need to be reviewed by the Office of Health Assessment and Evaluation's Rapid Assessment, Evaluation and Training (RATE) team. RATE review should be obtained prior to submitting an amendment application to the IRB. To request Rate review, please submit your project protocol [must follow this template] and survey(s) to irb@ph.lacounty.gov. IRB staff will forward the documents to RATE. The requestor will be contacted via email with the results of the RATE review. Save this email confirmation as a PDF document and upload it to your IRB application. If you make changes to your protocol and/or survey(s) in response to RATE feedback, only include "clean" versions (no comments or tracked changes) with your IRB application.

- *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.

## Amendment application checklist

☐ **Signatures**

The Principal Investigator(PI)/project lead, Co-PI (if applicable), and DPH/DHS liaison (if applicable) will need to provide their signature throughout the amendment application 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.

☐ **Summary of changes**

The amendment application will require a summary of all changes that are being requested as part of the amendment application (300 word limit).

☐ **Protocol**

Include both "tracked changes" and "clean" (i.e., without any comments or markings) 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.

☐ **New documents**

You will need to provide with your application any new documents you are adding to your project ("clean" versions of new documents only). This includes any documents that will be used to recruit participants, obtain informed consent, or collect data. Include any translated versions of study documents with your application, as applicable.* 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.

☐ **Modified versions of IRB-approved documents**

All previously approved documents (including consent forms, recruitment materials, surveys, interview scripts, etc.) that are being modified as part of the amendment must be included with the application. You must provide both "tracked changes" and "clean" versions of each document so that IRB staff are able to compare the differences. Include any translated versions of study documents with your application, as applicable.* If your amendment includes a change in funding amount or source, please include a revised budget with your application.

☐ **HIPAA individual authorization (if 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.

☐ **New personnel credentials**

If you are changing the Principal Investigator (PI)/project lead and/or the Co-PI, you will need to provide the following documentation for the new PI/project lead and/or Co-PI: professional qualifications such as a resume/CV, current Human Subjects Protection Training certification, and current HIPAA Training certification. If you are adding any other new personnel to your project, you will be required to provide the following for each new personnel: current Human Subjects Protection Training certification and current HIPAA Training certification. If any new personnel (including PI/project lead and Co-PI) are DPH badgeholders (employee #s begining with "c" or "e"), you will also need to provide their Cybersecurity training and Privacy Awareness training certifications. Please refer to the Training page on the IRB website for more information about training requirements.

☐ **Data Use Agreements**

Depending on whether your amendment involves the addition of the collection or accessing of data that was not previously approved, PIs/project leads will coordinate, as appicable, with their program's Contracts and Grants Liaisons to obtain appropriate data use agreements for the use of DPH or DHS data and/or data accessible to but not owned by DPH/DHS (such as data provided by the CA Dept. of Public Health). DUAs that are being added in an amendment should be uploaded in the "New Documents Not Prevously Approved" section of the amendment application.

☐ **Documentation of PHIS Information Security Office approval (if applicable)**

If you are adding any new personnel who are outside contractors (i.e., non-DPH staff) AND the project project involves collecting/working with Personally Identifiable Information (PII)/PHI, Public Health Information Systems (PHIS)-IT will need to approve of the software (and versions) you intend to use with the PII/PHI data. 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. You must work with PHIS-IT to create a secure folder that is only accessible to staff working with data (if this has not previously been done). You will receive a confirmation email from PHIS-IT when your request is approved. A PDF of the email confirmation should be included with your IRB application. Please allow up to 1 week to obtain PHIS approval.

## Making changes to your IRB application in IRBManager

An application in process can only be modified when it is in the "Data Entry" stage. If you need to make changes to an application that is no longer in the "Data Entry" stage, please contact IRB staff via email. Please refer to the following figure for a description of the IRBManager application process:
http://www.publichealth.lacounty.gov/IRB/Docs/IRBManager_process.pdf

## * Regarding translation of study materials

The IRB must first approve the original English document before a document can be translated. Any proposed translations should be noted in the protocol. When the translated documents are available, an amendment application should be submitted to the IRB for approval of the translated materials.

**NEW:** 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