

Department of Public Health Institutional Review Board  
313 N. Figueroa St., Room 127  
Los Angeles, CA 90012  
Email: [irb@ph.lacounty.gov](mailto:irb@ph.lacounty.gov)  
<http://publichealth.lacounty.gov/irb/>

## **Checklist of Items You Will Need to Submit a New IRB Application**

**REMEMBER: Project activities cannot begin until an official approval letter from the IRB has been obtained.**

- **For projects originating in DPH, involving DPH staff/clients, or funded by DPH:** documentation that surveys have undergone review by the Office of Health Assessment Rapid Assessment, Evaluation and Training unit (RATE) is required. RATE review of surveys is required per DPH policy 117, and should be obtained **prior to submitting** an IRB application. To comply with this requirement, please submit your study protocol (must follow this template) and survey(s) to [irb@ph.lacounty.gov](mailto:irb@ph.lacounty.gov). and IRB staff will forward the documents to RATE. The study contact will receive an email response from Dr. Lisa Smith confirming RATE review has been completed. After addressing RATE feedback, clean copies of your revised survey and/or protocol along with a PDF of the email from Dr. Smith should be uploaded to your IRB application in IRBManager.
- **For projects originating in DHS:** documentation that the project has undergone DHS Research Oversight Board (ROB) review and has been assigned an ROB category is required. ROB review should be obtained **prior to submitting** an IRB application. To comply with the ROB review requirement, please submit all project materials including the protocol (must follow this template) to [irb@ph.lacounty.gov](mailto:irb@ph.lacounty.gov) and IRB staff will forward it to the ROB for review. The study contact will receive an email with the result of the ROB review. A PDF of the email (including the assigned category) should be uploaded to your application in IRBManager.

### **Failure to obtain either RATE or ROB review will delay the IRB review process!**

- **Division Chief/Program Director approval.** You will need to name your Division Chief/Program Director on your application. They will receive automated emails from the IRBManager system with instructions for providing their required signature(s) as needed during the review process. Please ensure they check their email (including spam/junk folders) for any notifications.
- **Principal investigator(PI)/project lead and Co-PI signature.** The PI/project lead and Co-PI will receive automated emails from the IRBManager system with instructions for providing their required signature(s) as needed during the review process. Please ensure they check their email (including spam/junk folders) for any notifications.
- **DPH/DHS liaison signature (if necessary).** If the Principal Investigator/Project lead and Co-PI are not affiliated with the County (e.g., if they are from an organization that is external to the County such as a university), a permanent DPH/DHS staff member will need to be designated as DPH/DHS liaison on the electronic application. The DPH/DHS liaison will receive automated emails from the IRBManager system with instructions for providing their required signature(s) as needed throughout the review process (this may occur multiple times). Please ensure they check their email (including spam/junk folders) for any notifications.
- **Informed Consent forms** including any scripts that will be used for obtaining effective consent, e.g., verbal consent, consent language embedded in a data collection instrument, simplified written consent, or a strong justification for a waiver or alteration to documentation of informed consent requirements. Include any translated versions of consent forms/scripts with your application, if available.\*

- **HIPAA individual authorization or a strong justification for a waiver of HIPAA authorization.** Collection and/or access of PHI must be limited to the “minimum necessary” to achieve the purpose(s) of the investigation.
- **Professional qualifications, e.g., Curriculum Vitae/resume or other supporting information to document that key personnel are qualified to conduct the research activity.** Volunteers, contractors and students are permitted to be principal investigators so long as the Co-PI is a permanent DPH or DHS staff.
- **Research Protocol.** The protocol must be in the same format as the template posted on our webpage.
- **Lay summary.** This should contain a concise and non-technical description of the project, similar to an abstract in prose form and no more than 500 words.
- **Materials used for recruitment, e.g., fliers, scripts for emails/text messages, social media posts, reminder email scripts, etc.** Include any translated versions with your application.
- **Budget.** Include an explanation of any commitment of County resources and/or in-kind funding or, as applicable, an explanation for why a budget is not available.
- **Certificates of Human Subjects Protection Training for all study personnel.** This requirement can be satisfied by completing either 1) the free web-based training offered by CITI (see the IRB Trainings page for more information), or 2) the IRB’s Human Subjects Protection virtual training currently offered on a quarterly basis. Certificates are valid for 3 years from certificate date.
- **HIPAA Training Certificate for all study personnel.** County staff must complete the HIPAA for Covered Entities Training available on the TalentWorks website. Non-County staff may complete the web-based HIPAA course offered by CITI (see the IRB Trainings page for more information). Certificates are valid for 2 years from certificate date.
- **Data collection instruments, including surveys, focus group and interview questions and scripts.** Include any translated versions of instruments with your application, if available.\* Please make sure all supporting materials and/or appendices are clearly labeled with a title/heading at the top.
- **Documentation of PHIS IT approval for software use.** After answering a set of data security-related questions on the IRB application, a help ticket will be automatically created with PHIS to request approval for each 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 data. You will receive an email from PHIS confirming that any software (both the type and version) you intend to use in your project is approved for the specified use. A PDF of the email confirmation should be uploaded to your application. ***Please allow up to 2 weeks to obtain PHIS approval. Please anticipate longer turnaround times for non-standard County software applications.***
- **Laboratory Review Form.** This is only required if using a DPH lab. Please refer to our website for a copy of the form.

**\* 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](mailto: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>