

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. 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 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. If minors will be involved in the project, parent/guardian permission forms and minor assent

forms at appropriate reading levels should be included with the application. Parent/guardian permission forms should be at no greater than an 8th-grade reading level; teen assent forms (for ages 13-17) should be at no greater than a 6th-grade reading level; child assent forms (for ages 7 to 12) should be at no greater than a 4th-grade reading level. Reading grade levels of documents can be checked using the Microsoft Word Editor feature. Include any translated versions of consent or assent forms/scripts with your application, if available.

- **HIPAA individual authorization or a strong justification for a waiver of HIPAA authorization.** If HIPAA authorization will be obtained, you must use the HIPAA Authorization form posted on the IRB website (Forms and Templates page). 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 300 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, if available.*
- **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 OHRP (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. Please verify all certificates to make sure they correspond to the correct training and are uploaded in the proper location.
- **HIPAA Training Certificate for all study personnel.** County staff must complete the HIPAA for Covered Entities Training available on the TalentWorks website. Certificates are valid for 2 years from certificate date. Please verify all certificates to make sure they correspond to the correct training and are uploaded in the proper location.
- **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 you submit your 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 included with

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.

Note: 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**

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).

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>