County of Los Angeles Public Health

Department of Public Health Institutional Review Board
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Email: 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.

Before you submit an IRB application

- ***Projects originating in DPH, involving DPH staff/clients, or funded by DPH:***
  We are no longer requiring surveys to be reviewed by Office of Health Assessment and Epidemiology (OHAE) Rapid Assessment, Training and Evaluation unit (RATE). Please ensure your survey has been reviewed and approved by program leadership and subject matter experts in your program. If your program does not have this expertise and you would like help at any point in the creation of your survey, please contact OHAE Director, Dr. Megha Shah, who will determine the best team in OHAE to assist you.

  Your survey and project may need IRB approval if it involves research, evaluation, needs assessment or certain public health surveillance. If you have questions about whether or not your project needs IRB approval, please contact the IRB office at: irb@ph.lacounty.gov.

- ***Projects originating in DHS:***
  Your IRB application will need to include documentation that the project has been approved and assigned a category by DHS' Research Oversight Board (ROB). To comply with the ROB requirement, please submit all project materials including a project protocol [must follow this template] to irb@ph.lacounty.gov and IRB staff will forward it to the ROB for review. Results of the ROB review will be communicated via email. Save this email confirmation as a PDF and upload it to your IRB application.

Failure to obtain ROB documentation will delay the IRB review process!

New IRB application checklist

☐ **Division Chief/Program Director signature**

You will need to list your Division Chief/Program Director on your application. If they do not already have a "Contact" in the IRBManager system, you will need to create one for them (refer to the IRBManager user manual). They will receive automated emails from the IRBManager system with instructions for providing

their required signature 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 (if applicable) signatures**

The PI/project lead and Co-PI (if applicable) 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. Volunteers, contractors and students are permitted to be the PI/project lead so long as the Co-PI is a permanent DPH or DHS staff.

□ **DPH/DHS liaison signature (if applicable)**

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 IRB application. The DPH/DHS liaison will receive automated emails from the IRBManager system with instructions for providing their required signature as needed throughout the review process. Please ensure they check their email (including spam/junk folders) for any notifications.

□ **Protocol**

The protocol is a document which describes your project in detail. The protocol must follow the template posted on our webpage.

□ **Informed Consent forms**

All forms that will be used to document informed consent of participants must be included with your IRB application. In addition, any scripts that will be used for obtaining effective consent (e.g., consent language embedded at the beginning of a data collection instrument), verbal consent, or simplified written consent, should also be included with your application. If you are seeking a waiver or alteration to documentation of informed consent, you will need to provide a strong justification in your application. If minors will be involved in the project, parent/guardian permission forms and minor assent forms at appropriate reading levels should be included. 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 2nd grade reading level. Reading grade levels of documents can be checked using the Microsoft Word Editor feature. Please refer to our website for more information about informed consent.

Effective Consent

For projects using an effective consent, language about voluntariness is required, such as:

> *Your participation in this project is entirely voluntary. You can choose to participate and withdraw at any time without penalty. You can refuse to answer any questions.*

Or (if the project involves minors):

> *It is up to you if you want to be in this project. You will not get in trouble if you choose not to be in the project. If you choose to be in the project, you can change your mind and stop at any time. You do not have to answer any questions you do not want to.*

In addition to language about voluntariness, the effective consent should include a statement about whether the data collected about and/or from the participant will be anonymous or, if not, kept confidential. Confidential information is private information that can be linked to an individual, but is not shared with anyone else without the individual's permission. Anonymous information is information that cannot be linked to an individual (i.e., no Personally Identifying Information [PII] or Protected Health Information [PHI] collected).

□ **HIPAA individual authorization (if applicable)**

If your project will collect/access Protected Health Information (PHI), you will need to obtain authorization from participants using the HIPAA Authorization form posted on the IRB website (Forms and Templates). Please remember that collection and/or access of PHI must be limited to the "minimum necessary" to achieve the purpose(s) of the project. If you are seeking a waiver of HIPAA individual authorization, you will need to provide a strong justification in your application including a description of how the research could not be practicably carried out without the waiver. Convenience is not an adequate justification for granting a waiver of HIPAA authorization.

□ **Professional qualifications**

You will need to include a Curriculum Vitae/resume for the PI/project lead and the Co-PI (if applicable) in order to show that they are qualified to conduct the research activity. A CV/resume is not required for other key personnel.

□ **Lay summary**

You will be asked to provide a lay summary with your IRB application. This should be a concise and non-technical description of the project, written in a format similar to an abstract (in prose form and not a bulleted list), and a length of no more than 300 words. Please do not include any references in the lay summary.

□ **Data collection tools**

Any tools such as surveys, focus group scripts, interview questions, intake forms, etc., that will be used to collect data from or about participants must be included with your application. Please make sure all supporting materials and/or appendices are clearly labeled with a title/heading at the top. Include any translated versions with your application, if available.*

□ **Recruitment materials**

Include with your application any materials that will be used to recruit participants for your project such as flyers, scripts for emails/text messages, social media posts, reminder email scripts, etc. Include any translated versions with your application, if available.*

□ **Budget**

A budget or an explanation for why a budget is not available (such as an explanation of any commitment of County resources and/or in-kind funding, as applicable).

□ **Human Subjects Protection Training Certification**

All key personnel must have current Human Subjects Protection Training certification. This requirement can be satisfied by completing either 1) the 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 the certificate date. Please verify all certificates to make sure they correspond to the correct training and are uploaded in the proper location.

□ **HIPAA Training Certification**

County staff must complete the HIPAA for Covered Entities Training available on the TalentWorks website. Non-County personnel should complete the HIPAA training course available on the CITI website. Certificates are valid for 2 years from the certificate date. Please verify all certificates to make sure they correspond to the correct training and are uploaded in the proper location.

□ **Cybersecurity and Privacy Awareness Training Certification (if applicable)**

DPH staff who are badgeholders (employee #s beginning with "c" or "e") are required to complete a Cybersecurity training and a Privacy Awareness training on an annual basis. If any key personnel on your project are DPH badgeholders, you will need to include the certificates of completion for the two trainings with your IRB application.

□ **Human Subjects Considerations and Big Data Research training**

If your project involves Artificial Intelligence (AI)/machine learning/predictive analytics, all personnel, including the PI and co-PI, must complete the Human Subjects Considerations and Big Data Research training module available on the CITI website. To access this module, you will need to enroll in either the Biomedical or Social & Behavioral course and then select the Supplemental module. If you have already satisfied the Human Subjects Research Protection training, you do not need to complete all of the modules – only complete the Supplemental module. You will not receive a certificate of completion specifically for this module so you will need to upload your CITI transcript with your IRB application as documentation that the module was completed.

□ **Documentation of PHIS-ISO approval for software use (if applicable)**

Public Health information Security (PHIS)-Information Security Office (ISO) approval for software use is required for DPH projects if your project meets one of the following two criteria:

1. the project involves non-County personnel AND Protected Health Information (PHI)/Personally Identifying Information (PII); or
2. the project involves DPH staff who are using non-County-approved devices/software.

DPH employees using County approved devices/software do not need PHIS-ISO approval whether or not they are collecting/accessing PII/PHI.

To obtain PHIS-ISO approval

For DPH projects, after you submit your IRB application, a help ticket will be automatically created with PHIS-ISO. You must work with PHIS-IT to create a secure folder that is only accessible to staff working with data. 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.

For DHS projects, applicants should contact DHS' Information Security Officer, Vahe Haratounian, at vharatounian@dhs.lacounty.gov to obtain security approval. A copy of the email from Vahe confirming approval should be saved as a PDF and included with the IRB application.

□ **Memoranda of Understanding (MOUs)/Data Use Agreements (DUAs)**

When needed, PIs/project leads will coordinate 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). If any MOUs or DUAs are in place for your project please include these documents in the Additional Documents section of the application.

□ **Laboratory Review Form**

This form is only required if using a DPH lab. Please refer to our website for a copy of the form.

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/Figure2_IRBManagerProcess_jul72024_v3.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