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

# Checklist of Items You Will Need to Submit a Progress/Final Report

**REMEMBER:** Progress reports are due for all projects even if no expiration date was noted on the initial approval letter. Progress reports must be submitted annually using the IRBManager portal. Any project that does not submit an annual progress report at least 2 weeks before the due date (stated on the most recent approval letter) will be automatically closed by the system and a new application will need to be submitted in order to open the study. Please contact the Office of the IRB at irb@ph.lacounty.gov if you anticipate any challenges with meeting due dates. Refer to Section 6 of the IRBManager User Guide (available here) for instructions about submitting a progress report using the portal.

## Final Reports

If your project is complete (including all data analyses), you must submit a final report so the IRB can close out the project. To submit a final report, please follow the same steps as you would for submitting a progress report. When you are asked to indicate the current study status on the progress report, please select the response option "study completed, final report attached". You will be prompted to upload a final report document in a later section of the progress report.

## Progress Report checklist for ongoing projects

□ **Current status of the project**

You will be asked to indicate the current status of the project in the progress report. If the project is complete (including all data analyses), select the "Study completed, attach final report" response option. You will be prompted to upload a final report document in a later section of the progress report.

□ **Number of project participants**

You will be asked to enter the total number of people that have participated in the project since the initial IRB approval (this includes focus group participants, survey respondents, etc.). You will also be asked to enter the number of people that participated in the project since the last progress report (if this is the first progress report being submitted, this number would be the same as the total enrollment since initiation of study). Lastly, you will be asked to enter the number of people you will recruit/expect to

participate in the future, if any. If “Active, continues to enroll subjects” is selected for the study status, the number of future participants cannot be 0 (or left blank).

□ **Participants withdrawn from the project**

You will be asked to note whether any participants were withdrawn from the project and the reason(s) for their withdrawal. Please do not include any Personally Identifying Information (PII) or Protected Health Information (PHI) about participants.

□ **Adverse Events**

You will be asked to describe any adverse events that have occurred since the start of the project or the last progress report (whichever is more recent). Your response should note whether the adverse event was reported to the IRB within 7 days of the project team becoming aware of the event as required by the IRB. If the adverse event was not reported to the IRB within the required timeframe, you must provide an explanation for why that is the case and complete a Reportable Events form (refer to Section 12 of the IRBManager user guide). Please note, prompt reporting to outside agencies may be required for certain types of adverse events.

□ **Summary of Activities**

You will be asked to provide a summary of activities that have been completed as part of the project since the initial approval or the last progress report, whichever is more recent.

□ **Summary of Results/Findings**

You will be asked to provide a brief summary of any results/findings of interest (if available) since the start of the project or the last progress report, whichever is more recent.

□ **Changes to risks**

If there have been any changes in the risks to participants or in the balance between the risks and benefits related to participation, you will be asked to describe any such changes.

□ **Health Equity data**

If your project indicated on the initial IRB application that health equity data would be collected as part of the project, you will need to upload a document that contains the health equity data you committed to collecting. Please note that, on the progress report, the health equity data variables noted on the initial application will be autopopulated in this section for your reference. If this section of the progress report is blank (i.e., nothing is autopopulated), you can disregard this section and proceed to the next question.

□ **Community Engagement**

You will be asked to describe how the community has been involved in your project. This includes the involvement of community members in designing the project or in recruitment/consenting/data collection related to the project. This section should also include a description of how results/findings, if

available, have been disseminated to the community. If the community has not been involved in any aspect of the project, you must provide a reasonable justification for why that is the case.

□ **Barriers to health equity SOP**

You will be asked to describe any barriers project staff have faced when trying to comply with the guidance outlined in the IRB's Health Equity SOP/policy. If your project did not address health equity, please enter "N/A" in the space provided.

□ **Publications/abstracts**

If any abstracts, publications, or presentation materials have been created using the findings from the project, please include copies of these materials in the space provided.

□ **Required Signatures**

The PI/project lead, Co-PI (if applicable), and DPH/DHS liaison (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.

## 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