



Best practices for projects where IRB oversight is not required

(IRB APPLICATION NOT NEEDED)

The Office of the IRB is working to reduce the burden on programs and to educate and empower programs to oversee their own low risk projects that do not meet the federal regulatory definition of “research”. Thus, we have revisited our requirements for projects that do not need IRB oversight, exceptions listed on page 6. During this transition period, we will be evaluating our educational materials - before implementation of your project, please contact the Office of the IRB via email IRB@ph.lacounty.gov to let us know your self-determination as well as if you have questions regarding whether your project needs IRB oversight. The Office of the IRB makes the final determination.

Does my project involve vulnerable populations?

Persons are considered vulnerable if they are at greater risk of coercion or undue influence to participate in data collection activities such as surveys, focus groups, listening sessions, or interviews.

Projects involving these **four vulnerable populations** require IRB oversight:

- ✓ minors
- ✓ currently or formerly incarcerated persons, parolees or probationers
- ✓ pregnant persons
- ✓ individuals with impaired decision-making capacity

Projects may still involve vulnerable populations but **do not necessarily need IRB oversight** such as:

- non-English speaking participants
- participants experiencing homelessness
- economically disadvantaged participants
- emancipated wards
- participants with terminal illnesses
- medical vulnerable (e.g., persons with life-impacting disorders/illnesses)
- elderly participants (65+)

Although such projects do not necessarily require IRB oversight, you may need to implement additional protections to ensure their ethical treatment.

WHAT ABOUT CONSENT?

1

Consent language should be communicated before any data collection activity. For self-administered surveys, consent language should be included at the beginning of the survey. For focus groups, listening sessions, and interviews, consent language should be communicated verbally. Participants should be given the chance to agree verbally that they consent.

2

Consent information should contain the following **three elements**:

- ✓ Your participation in the project is entirely voluntary
- ✓ If you choose to participate, you can end your participation at any time without penalty
- ✓ You can skip/refuse to answer any questions/activities

3

Participants should be told if they will remain anonymous or whether their data will be confidential or shared with anyone other than project staff, for example, where mandatory reporting requirements are applicable.

Anonymous: Protected health information (PHI) or personally identifiable information (PII) is not collected.

Confidential: PHI or PII that can be linked to a participant is collected/accessed but not shared with anyone other than project staff without the participant's permission.

4

Participants should be told if they will receive any payments for their participation and/or reimbursement for expenses such as parking fees, travel expenses, and childcare. The consent process should also explain how and when participants will receive payment.



Focus Groups & Listening Sessions

Participants should be given information in advance of the focus group or listening session including:

- ✓ who the other participants may be
- ✓ where the group will meet
- ✓ how long the session will last
- ✓ whether the session will be recorded



What about Protected Health Information (PHI)?

Projects collecting and/or accessing PHI must comply with DPH HIPAA policies (available [here](#)). These projects do not necessarily need IRB oversight.



Are my project materials clear?

Project materials should be clear, accessible, and at an appropriate reading grade level for the intended audience.

This includes:

- recruitment materials
 - flyers
 - consent language and scripts
 - focus group introductions and scripts
 - data-collection instruments such as surveys
-
- ✓ use common, everyday language
 - ✓ avoid jargon/technical terms

Materials should be translated into languages spoken/read by the participants.

For general LA County participants:

- ✓ reading grade level should not exceed 8th-grade
- ✓ materials should be translated at least into Spanish

For tips and tricks on creating readable documents, please click [here](#).

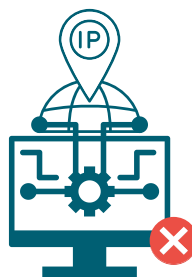
What should be included in surveys?

Include standard demographic questions in your survey using the format described in the Chief Science Office SOPs (available upon request):

- ✓ Race and ethnicity (CSO-002)
- ✓ Sexual orientation and gender identity (SOGI) (CSO-003)
- ✓ Disability status (CSO-007)



Each question should include "Prefer not to answer" and "Don't know" response options.



If an online survey will be anonymous, make sure any software you are using is not collecting IP addresses.



What if participants have questions?

The Project Lead's contact information should be included in all project materials given to participants to let them know whom to reach out to for inquiries or concerns.

Health Equity and Communities Matter!



Projects should engage the community by:

- ✓ getting input from community members from Day 1 to guide your projects
- ✓ asking opinions of key informants in the community to make sure your project is culturally sensitive
- ✓ asking community members to help with recruitment
- ✓ asking community members to help with administering surveys/data collection and/or analyzing data
- ✓ debriefing participants after data collection
- ✓ sharing findings with the community/participants
- ✓ applying findings to policy decisions at varying levels

To learn more about how you can address health equity and include the community in your project, please attend the IRB's biannual Community Engagement in Research, Evaluation, and Related Activities training and refer to the following DPH Standard of Practice:

<http://intranet.ph.lacounty.gov/ph/PDFs/PHDirector/ChiefDeputyDirector/IRBSOP-008.pdf>

⚠ A Note on Sensitive Topics

Topics such as substance use disorder, illicit drug use, gun violence, intimate partner violence and HIV may be considered sensitive. Beliefs, opinions, and knowledge levels may be less sensitive than personal use/experience. Although such projects do not necessarily require IRB oversight, you may need to implement additional protections to ensure participants are not coerced, and are treated ethically. Also, you still have the option of seeking out IRB oversight for any such project.

What about incentives?

Compensation should match the time and effort of participants. The payment should not be too high that it coerces or influences participants unduly into participating in activities they would otherwise strongly object to based on personal values or beliefs.

Compensation should be equitable - selective incentives where only a limited number of participants receive compensation, such as only the first 50 participants receiving a gift card, should not be used.

Note: California state law ([Cal. Pen. Code § 319](#)) places restrictions on the use of raffles, lotteries, and drawings. Generally, participation in any of these three schemes cannot be conditioned on providing some form of consideration.

If you would like to use any of these to compensate participants, we recommend the following:

- ✓ the term “drawing” should be used since “lottery” or “raffle” imply purchase of tickets by participants
- ✓ individuals should be given equal compensation by having an equal chance of winning including those who are asked to participate in a proposed activity but decline, those who consent/assent to enroll in the project, or those who enroll but withdraw from the project
- ✓ make sure to include any individual not recruited but who wishes to take part in the raffle, lottery, or drawing
- ✓ there should be a fair method of choosing and notifying the winner

For further guidance and resources, please visit the DPH IRB website at

<http://publichealth.lacounty.gov/irb/>



EXCEPTIONS TO DPH IRB SUBMISSION

(IRB APPLICATION NOT NEEDED)

If your project fits one of the categories below and does not involve the following four vulnerable populations: minors, currently or formerly incarcerated persons, parolees or probationers, pregnant persons and those with impaired decision making, it does not require IRB oversight. *In addition, any project that is considered “research” by the federal regulations and/or involves the use of AI requires IRB oversight.*

1. Program evaluations for internal use with no intention to publish
2. Quality improvement (QI) projects
3. Needs assessments
4. Focus groups
5. Listening sessions
6. Customer satisfaction surveys
7. Does not involve humans (e.g., animals only, some lab studies)
8. Legally mandated reporting/surveillance and certain **public health surveillance and practice**
9. Information collected/charted as part of clinical care
10. Anonymous meeting or training evaluations
11. Staff assessments or other internal queries that pertain to core job duties and skills
12. Environmental or criminal investigations
13. Authorized operational activities in support of criminal justice or criminal investigative activities or defense/national security
14. Safety and injury surveillance activities designed to enable DPH to identify, monitor, assess, and investigate potential safety signals for a specific product or class of products (e.g., the surveillance activities of FDA's Adverse Event Reporting System)

If your project changes to include research or any of the four vulnerable groups mentioned above, an IRB application must be submitted.

During this transition period, the Office of the IRB will be evaluating our educational materials - before implementation of your project, please contact us via email IRB@ph.lacounty.gov to let us know your self-determination as well as if you have questions regarding whether your project needs IRB oversight. The Office of the IRB makes the final determination.