

Design a Partnered Consent Form

UCLA CTSI Community Engagement & Research Program
Partnered Research "How To" Series



PROBLEM

During project development, community partners felt that the standard consent form template was too complex and needed to be more participant-friendly. Our project needed to modify the consent form to reflect the views of community members, while still meeting requirements for IRB approval.

PROCESS

We used the following process to develop a participant-friendly, lay-language consent form that would be administered by trained research assistants.

Step 1. Consult with institutional IRB

The university IRB supported the revision process, but said some of the consent language was required and could not be changed. While the required text could not be altered, words or phrases could be added to clarify any confusing terms.

Step 2. Draft modified consent form

We drafted the text to address each one of the following IRB required components:

- Contact information for community and academic investigators and the Office for the Protection of Human Subjects
- Purpose of study
- Procedures and risks
- List of physical and laboratory data collected
- Anticipated benefits for the participant and the community
- Compensation for participation
- Privacy and confidentiality of the data collected
- Rights of research participants
- Consent to be contacted by researchers

Healthy Community Neighborhood Initiative (HCNI)

A community-partnered participatory research project

Purpose: Address health disparities in a low-income African American and Latino community in South Los Angeles

Partners: UCLA CTSI, Los Angeles Urban League, Healthy African American Families II

Project components: consent form, adult interview, health screening, and laboratory data

Timeframe: household surveys conducted in South Los Angeles between May 2012 and December 2013

[More information on HCNI:](#)

http://ctsi.ucla.edu/patients-community/pages/research_projects#greenic



Step 3. Community residents reviewed the modified consent form

The revised consent was reviewed by clients from the community agencies. Two separate review sessions (2-3 attendees each) were conducted (one in English and another in Spanish) at a community partner site.

After being briefed about the study and the purpose of the consent form, participants were asked to review the form and respond to the following questions:

- Is the text jargon-free and understandable?
- Is the text comprehensive, culturally appropriate, and relevant?
- Does the consent form protect the rights of participants as well as the privacy and security of the data collected from them?

Step 4. Synthesize community feedback

After community residents commented on the form, they worked with study team to propose revisions, including clarifications to required text. (See insert)

Step 5. Revise draft

After the review session, the study team incorporated the proposed revisions into the consent form. The community and academic leadership reviewed and approved the changes and the study team sent the form to the IRB.

Step 6. Obtain IRB approval and field test revised consent form

The IRB reviewed and approved the revised consent form. The study team fielded the consent form during the pilot phase of the household survey. All pilot survey participants reported that they understood the consent form and had no concern or changes to request. However, some survey participants wanted a frequently asked question (FAQ) sheet to keep as a reference and to help recruit others to the study. The study team drafted the FAQ sheet, which was reviewed by the community and academic leadership and approved by the IRB.

CONCLUDING THOUGHTS

The partnered design of the HCNI consent form shows that it is possible to bring together community and academic knowledge to identify problems and work on appropriate and acceptable solutions for the community.

"If you want to go fast, go alone. If you want to go far, go together." - African Proverb

UCLA CTSI Community Engagement and Research Program (CERP)

Develops, implements, and refines models of community engagement and community capacity building, and facilitates research collaborations between academics and community partners.

Services:

Dissemination of research results ▪ Advice on study design and implementation
Connecting investigators and community ▪ Grant preparation and training

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Issues identified by community residents and changes made to consent form text

| Issues Identified | Changes Made |
|--|---|
| Lack of clarity about the compensation given to study participants | ✓ Include a payment chart showing compensation for each study component |
| No mention of whether participants would have access their DNA data if the research team made the decision to analyze DNA information from bloodspot samples | ✓ Text added explaining that findings of any DNA analysis will not be shared with participants unless required by law |
| Lack of clarity about losing right to privacy and confidentiality under certain circumstances | ✓ Text added explaining that the waiver applies to cases of suspected child and elderly abuse |
| No option offered to participants to have their health test results communicated to their physician | ✓ Add option to send health test results to designated physician |
| The word choice of "tissue" was too technical and could be confused with skin | ✓ Add the phrase "also known as blood" to clarify the meaning of "tissue." |

Additional Resources on community engaged research:
<http://ctsi.ucla.edu/patients-community>



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