California Initiative to Advance Precision Medicine

Equitable Consent Working Group
Draft Meeting Summary, February 2021

Existing laws and regulations related to informed consent

- Federal Law: Revised common rule ("common" because the same guidance appears in several different places in federal law). A recent update includes new language for broad consent for unspecified future use of biospecimens.
- California Protection of Human Subjects in Medical Experimentation Act, including the experimental subject's bill of rights
- California has an existing consent checklist that covers everything in state and federal law, but doesn't have an equity lens: https://oag.ca.gov/sites/all/files/agweb/pdfs/research/consent-checklist.pdf
- All of Us research program
- NIH Genomic Data Sharing policy: requires some features to be included in the consent form regardless if the samples are identified, deidentified, or protected health information

Project options

- Project suggestions fall into one or more major domains:
    - Community engagement
    - Content development/synthesis
    - Implementation science
    - Policy
- Create recommendations, a policy document, and/or a template for a California-centric universal consent.
    - Incorporate existing state and federal laws and regulations.
    - Seek out and address feedback, comments, suggestions, and criticism from stakeholders, including patient advocacy and community groups.
    - Dissemination and roll out: Governor's Office? Legislators? Universities? Community centers? Creation of the document needs to take the target audience into consideration.
    - Universality is difficult because organizations have their own legal teams, and there are several types of:
        - Research (low risk, high risk)
        - Data (identified, deidentified, genomic, images, left over medical samples)
        - Consent (broad, regular)
        - Use (academic, commercial, unspecified future use of biospecimens)

    - *All of Us* has three separate consents: general, EHR, and genomic.
    - Standardization of language could aid data sharing across entities.
    - Plain language increases a document's accessibility for all educational and literacy levels.
    - A consent form should serve all communities, and be available in several languages.
    - Clarify that the scope of the document is only for consent to participate in research, not to receive clinical care.
    - Perhaps limit the scope of the document/guidelines to genetic consent.
- Write consenting guidelines for staff at FQHCs (Federally Qualified Health Centers) and community clinics.
    - Academic and other research institutions already have training policies, but FQHCs and community clinics do not have the capacity to formally incorporate processes to protect human subjects in research. The staff aren't trained well enough.
    - Include ethical principles, an historical prospective, and an evaluation tool to ensure that the consenting process is respectful, meaningful, and educates and engages the community appropriately.
    - Staff need to understand the how, what, why, who.
    - A large body of literature exists about how to consent different communities. Should that information be synthesized to create a toolkit?
- Work with community-based organizations to help underrepresented minorities (URM) understand their role in research.
    - A consent document is useless if it doesn't increase participation of URM.
    - Prior to be consented, work needs to be done for URM to understand:
        - What research is.
        - How it impacts them, their loved ones, and the broader community.
        - Why they would want to engage.
        - What the consent process is.
        - Why they need to consent.
        - That the process is fair.
        - Why they should trust the researchers.
- Create or invite grantees to create video content to expand on the work of UCLA, or scale work that has already been done.
    - The funding situation for projects is not clear.

VIDEO: Universal Consent to use biological samples for research

- Electronic Informed Consent Video was developed in a partnership between the UCLA Clinical and Translational Science Institute, UC Davis, UCSF, UC Irvine, and UCSD.

- UCLA Precision Health Institute has customized this version of the video for their biobank to power precision health. It specifically seeks to gain consent to use leftover, de-identified biological samples from medical visits for research.
- The video has been translated into the six most common languages spoken by UCLA patients.
- Target should be 6th-7th grade reading level, but a 3rd grade level would be appropriate; this video is at 12th grade reading level.
- In addition to the required elements of basic consent, the video also states that:
    - UCLA may share data with researchers in academia, industry, and government.
    - The data can be used specifically for genomic analysis (required by new broad regulatory consent for unspecified future use).
    - Participants' health care providers will receive results of genetic tests that may have some baring on clinical care.
- There are ongoing studies looking at implementation of the video consent process across different patient populations. Outstanding questions include:
    - Do people actually understand the consent?
    - Are participants asking follow up questions?
    - What are the drivers of consent (assessed using cognitive surveys)?
    - What is the best way to integrate the research consent process into routine clinical care?
- Current law does not require UCLA to get consent to use de-identified data for internal use at UCLA, but consent does need to be obtained if the samples/data will be used in collaboration with industry. Those collaborations must be consented to specifically.
- Discussion:
    - The video could be made more compelling by including stories, and explaining why research is important (protecting the community, protecting loved ones, etc.).
    - The *All of Us* consent videos have been successful and participants like the video consent process; it is important to have assistance for those who have additional questions.
    - Cancer patients are generally ok with sharing samples, but other types of patients are more reticent, and unsure about security, insurance, and what the benefits are to themselves and/or their community.