Expansion of Universal Consent to our UCLA Patients

UCLA Clinical and Translational Science Institute, Embedded Clinical Research Innovation Unit

UCLA - Cedars Sinai Medical Center, Charles R. Drew University of Medicine and Science - Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center

The Challenge

Identifying a method of consenting that is cost-effective and efficient for the vast majority of UCLA Health's patient population to give them the opportunity to be part of UCLA Health's research endeavors. To facilitate this end, research and de-identified clinical data has been an important resource. Our challenge is to expand UCLA's Universal Consent for Biologic Samples (UCOB).

The Opportunity

When attempting to reach the UCLA adult patient population to complete a one-time consent process such as the Universal Consent, it is imperative to identify and innovative approaches needed to be developed to reach a broader background and health care utilization demographics. To do so, we engaged methods such as using our EHR portal patient contacts, in-person clinics, and outreach efforts but, in order to give patients the opportunity to complete the requested one-time process as conveniently as possible.

Background

A global consent for relevant biological samples was conceptualized in 2015 but has been initially way that it could only be presented to patients on paper. In 2014, we began the process of designing and implementing a video consent process through an EHR video portal where patients could authenticate their identity before selecting whether they wanted to share their normal samples or not. In 2017, a more optimized version of the EHR and video was released, adding the option for patients to opt-in for giving an extra blood tube for research collected as a chunk back to a clinical vignette. At that time, it was also approved as the institutional consent request of all patients to complete an electronic Universal Consent. Soon after the EHR video consent portal (McChat) version of the Universal Consent was created where patients can select to consent or opt-out of the routine venipuncture, we began by logging in their respective patient ID numbers to their video portal and they would be linked to the EHR portal to complete the consent process.

Method

To consent to

101 completed (% in parenthesis)

Opted-in Reasons Not at all A little Moderate Important *One patient didn't answer the question
0 (0) 2 (2) 4 (4) 94 (94)

Hoping to contribute to the cure of disease* 94 (94)

Phase 1 Video Consent

Comparison of Usefulness, Ease to Use and Trustworthiness between Two Pilot Phases Video Consent. (N=164)

Phase 1 (N=47)

Phase 2 (N=117)

Usefulness

9.8 (2.1)

8.9 (2.0)

Ease to Use

7.2 (1.9)

7.2 (1.8)

Trustworthiness

9.2 (1.7)

9.3 (1.8)

5-point Likert scale 1-not at all; 2-not really; 3-somewhat; 4-mostly, 5- very

Conclusion

In conclusion, a multi media approach to assure we are reaching UCLA Health's patient population is the only method that can give the way to uphold the consent requirements and ensure patient data consistency in the EHR-based, if used, to be a cost effective implementation of the institutional consent process.

Although the work we have put in to develop methods to optimize patient engagement around the Universal Consent for Biologic Samples, further work is in the way to refine the paperwork (also with a QR code linked to the web-based patient portal) to educate the community around the purpose of Universal Consent and how it relates to the future of translational medicine. Specifically barriers observed in our underrepresented low socioeconomic population. We have also next stage underway of the consenting process in our pediatric population, coming in 2022.

After the development of the electronic version of the Universal Consent, the ECRU team approached patients at random in various clinics or hospital settings to get their feedback on how to improve the portal. They found the portal was easy to navigate and how they could opt in or out. These were the initial results. This was important to allow patients' reactions and understanding of the consent.

Lessons Learned

Language should be available in English, Spanish, Mandarin, Farsi, Korean and Chinese.

The consent process must cover the UCLA Health patient population and minimize coercion and the need for follow-up.

The importance for clinic directors, managers, and administrators to be involved from the start of any consent process.

Assistance from volunteers and work study to assist high volume clinics.

Community Advisory Board feedback and contribution to development of consent language.

Community support and feedback in various modalities to improve the patient's experience and satisfaction with the process.

We have identified barriers in further need to educate the community around the purpose of Universal Consent and how it relates to the future of precision medicine.

The image above represents the home page of the external App developed for Universal Consent where patients complete the process on their own smartphone or web-based. The App production was developed in collaboration with: DataZen Software Inc.

If interested in learning more about UCLA's Universal Consent and ECRU’s involvement, please contact: apomaz@mednet.ucla.edu

Expanding the potential for informed consent in biologic samples was key to this study.

The video production module developed in collaboration with: DataZen Software Inc.

Dear valued UCLA patient,

We strongly encourage you to learn more about the UCLA Health's Universal Consent for Biologic Samples. We are always here to answer any questions or concerns you may have. Please feel free to contact us at apomaz@mednet.ucla.edu for more information.

Please be informed that this study is conducted in strict accordance with institutional and federal regulations to protect patient privacy and confidentiality.

Thank you for your commitment and support.

Sincerely,

The UCLA Health’s Universal Consent team