

EngageUC

Year 2 Update: Looking Ahead

Co-Directors

Elizabeth **Boyd**, PhD, Compliance, UC Riverside

Daniel **Dohan**, PhD, Health Policy & Social Medicine, UCSF

Sarah **Dry**, MD, Pathology, UCLA

Co-Investigators

Arleen **Brown**, MD, PhD, Medicine & CTSI, UCLA

Barbara **Koenig**, PhD, Bioethics & Anthropology, UCSF

Program Manager

Jennifer **Hult**, MPH, CTSI, UCSF

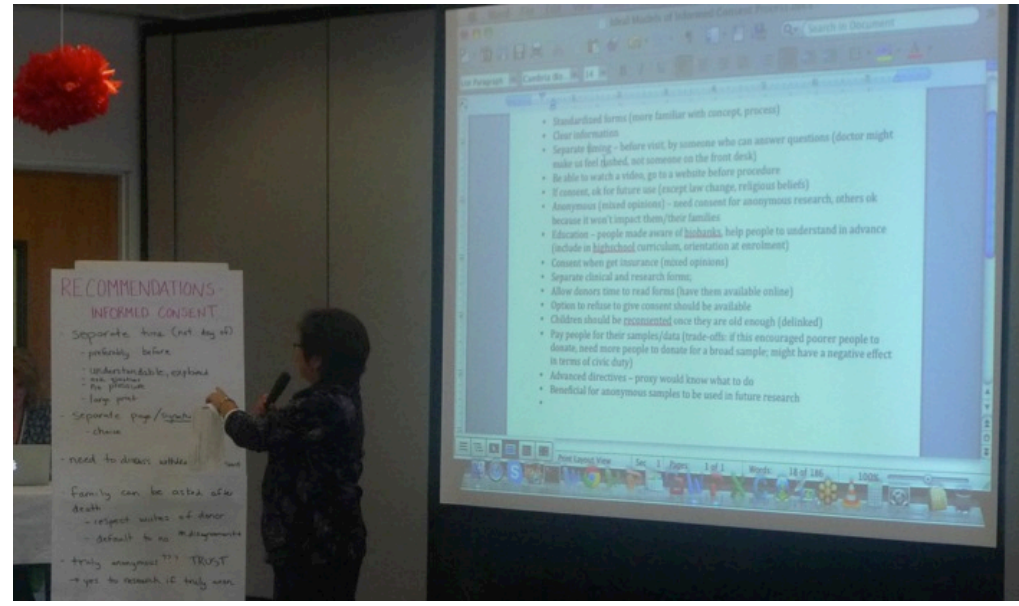
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Overall Goal: Ethical, Efficient, Sustainable UC Biobanking System

- Ethical
 - Aim 1, Stakeholder engagement
 - Identify how to build public support for biobank research
- Efficient
 - Aim 2, Compare methods for obtaining consent
 - Determine what works for obtaining informed consent
- Sustainable
 - Aim 3, Policy translation
 - Inform system-wide policies & action

Aim 1: Stakeholder Engagement

Deliberative Community Engagement



Biobank Governance and Oversight

Recommendation	San Francisco			Los Angeles		
	Vote ID#	# Yes	Full Vote	Vote ID#	# Yes	Full Vote
SECTION A - COMMUNITY GOVERNANCE						
The community [incl their needs, priorities] should be represented by a body.	A3	22	a3: 22/0/3	A2	25	25/1/0
A community body must have a meaningful role in the oversight of [UC] biobanks.	A1	24	24-0-1	A1	26	26/0
They should represent California's diversity	A4	23	23/1/1	A2	25	25/1
The public should be educated about bio-banking	A2	25	25-0-0	B1	25	25/1

SECTION B - TRUSTWORTHY OVERSIGHT						
Oversight should be conducted by the community ...	B16	21	21/2/2	B5	22	22/2/2
and by the IRB, the biobank, and UC.	B16	21	21/2/2	--	--	
and other unbiased stakeholders (e.g., scientists, medical professionals and lawyers)	--	--		B5	22	22/2/2
There should be monitoring and consequences for improper handling or misuse of data or samples.	B15	23	23/1/1	B2	26	26/0

The community should be represented by a body that has a meaningful role in the oversight of biobanks.

Members of this body should represent CA's diversity.

The public should be educated about bio-banking

There should be monitoring and consequences for improper handling or misuse of data or samples.

Oversight should be conducted by the community and other stakeholders.

Sharing Samples and Data & Returning Results

Recommendation	San Francisco			Los Angeles		
	Vote ID#	# Yes	Full Vote	Vote ID#	# Yes	Full Vote
SECTION D - Sample and Data Sharing						
UC can share [should support sharing] samples [and data] among [all] researchers provided...						
...good oversight (SF)/ethical governance (LA)	D27 & 29	22	27: 22/2/1, 29: 22/1/2	D1	25	25/0/1
...it advances research	D27 & 29	22	27: 22/2/1, 29: 22/1/2	--	--	
...it is for the public good.	--	--		D1	25	25/0/1
If data/samples are shared (outside of UC [SF]), results should be shared back to...						
... UC	D30	24	24/0/1	--	--	
...Research programs and clinical organizations	--	--		B3	23	23/2/1
SECTION E - RETURN OF RESEARCH RESULTS*						
Individuals should be able to choose to receive results or not.	B19	24	24/0/1	E2	23	23/2/1

UC can share samples with other researchers provided that there is oversight and it is for the greater good.

Results from this sharing should inform future research.

Donors should be able to choose to receive results or not.

Consent Process

Recommendation	San Francisco			Los Angeles		
	Vote ID#	# Yes	Full Vote	Vote ID#	# Yes	Full Vote
SECTION F - INFORMED CONSENT						
Consent must [should] be obtained when donor is less [not] stressed, worried or preoccupied	F36	24	24/0/1	F2	24	24/1/1
It should be obtained via interaction with a knowledgeable [and trusted] person [who has time to answer questions]	F42	24	24/1/0	F2	24	24/1/1
Consent forms must[should] be written clearly and use simple language [and large fonts, in the donor's preferred language]	F34	24	24/0/1	F1	25	25/01/

The format and language of consent materials should make the content easy to understand.

High levels of support – but no consensus – for obtaining informed consent for all biosamples used in research at UC campuses going forward.

The consent process should be initiated at a time of low stress for the patient by a knowledgeable, trustworthy individual; there should be ample time for discussion.

Aim 2: What Works to Obtain Consent?

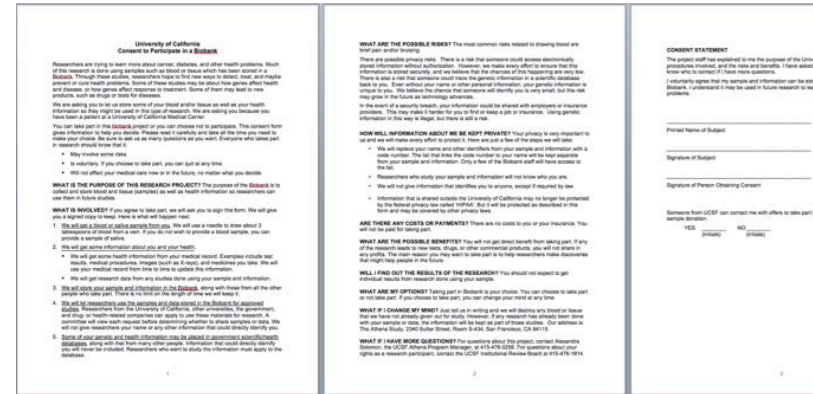
- Clinic-level randomization; 3-arm trial

1. Current form - baseline
2. Simplified form
3. Simple form + video

- Outcomes

- Uptake
- Staff burden
- Subject understanding

UCSF (in progress @ 2 clinics);
UCLA (expect to open soon);
UCSD (in discussion)



Aim 3: Translation into Policy

Nov 14 Stakeholder Workshop

- One-day workshop at UCOP
 - Biobankers and institutional officials from all 5 BRAID campuses
 - Community deliberants from LA & SF
 - Administrators from UCOP
- UC as a leader in responsible biobanking
 - Opportunity for stakeholders to meet & talk
 - Demonstrate grassroots interest and commitment
 - Potentially gain insights into next steps
 - 2024: Look back on this workshop as a starting point

Thanks...

- EngageUC Co-PI's
 - Steve Dubinett & Deborah Grady
- UC BRAID Executive Committee
 - Rachael Sak
- EngageUC staff
 - Giuseppe Cavaleri & Sarah Garrett UCSF
 - Brian Gardner & Arturo Martinez UCLA

NIH/NCATS UL1TR000004-07S2 (EngageUC)

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Opinions are ours and not those of NIH/NCATS or UC Office of the President.