EngageUC

Year 2 Update:
Looking Ahead

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NIH/NCATS
UL1TR000004-07S2
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**

### SECTION A - COMMUNITY GOVERNANCE

| Recommendation | San Francisco | | Los Angeles | |
|----------------|---------------|------------------|---------------|
|                | Vote ID# | # Yes | Full Vote | Vote ID# | # Yes | Full Vote |
| 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.*
### SECTION D - Sample and Data Sharing

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>San Francisco</th>
<th>Los Angeles</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC can share samples [should support sharing] among [all] researchers provided...</td>
<td>Vote ID#</td>
<td># Yes</td>
</tr>
<tr>
<td>...good oversight (SF)/ethical governance (LA)</td>
<td>D27 &amp; 29</td>
<td>22</td>
</tr>
<tr>
<td>...it advances research</td>
<td>D27 &amp; 29</td>
<td>22</td>
</tr>
<tr>
<td>...it is for the public good.</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>if data/samples are shared (outside of UC [SF]), results should be shared back to...</td>
<td>D30</td>
<td>24</td>
</tr>
<tr>
<td>... UC</td>
<td>--</td>
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</tbody>
</table>

### SECTION E - RETURN OF RESEARCH RESULTS*

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>San Francisco</th>
<th>Los Angeles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals should be able to choose to receive results or not.</td>
<td>Vote ID#</td>
<td># Yes</td>
</tr>
<tr>
<td></td>
<td>B19</td>
<td>24</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Recommendation</th>
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<th>Los Angeles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent must [should] be obtained when donor is less [not] stressed, worried or preoccupied</td>
<td>F36 24 24/0/1</td>
<td>F2 24 24/1/1</td>
</tr>
<tr>
<td>It should be obtained via interaction with a knowledgable [and trusted] person [who has time to answer questions]</td>
<td>F42 24 24/1/0</td>
<td>F2 24 24/1/1</td>
</tr>
<tr>
<td>Consent forms must [should] be written clearly and use simple language [and large fonts, in the donor's preferred language]</td>
<td>F34 24 24/0/1</td>
<td>F1 25 25/01/</td>
</tr>
</tbody>
</table>

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)
UC Research Opportunity Funds (Stakeholder Workshop)
Opinions are ours and not those of NIH/NCATS or UC Office of the President.