



# EngageUC: Engaging University of California Stakeholders for Biorepository Research



UNIVERSITY of CALIFORNIA · IRVINE



#### **ENGAGEUC**

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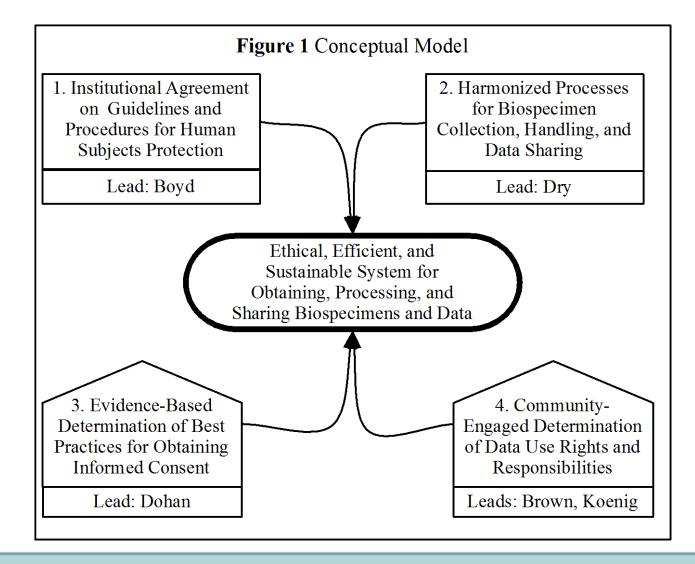
Engaging University of California Stakeholders for Biorespository Research

Elizabeth Boyd Daniel Dohan Sarah Dry

September 14, 2012



# Efficient, Ethical, and Sustainable System for Obtaining Biospecimens and Data





# **Organization**

#### Figure 3 EngageUC Leadership and Administration

#### **Principal Investigators**

S. Claiborne Johnston, MD, PhD, UCSF Steven Dubinett, MD, UCLA

#### **Program Directors/Co-Chairs**

meets weekly with Program Manager Sarah Dry, MD, UCLA Co-Chair Elizabeth Boyd, PhD, UCSF Co-Chair (Aims 1,3) Daniel Dohan, PhD, UCSF Co-Chair (Aim 2)

#### **Operations Committee**

meets at least monthly with Program Manager
Elizabeth Boyd (Institutional Relationships)
Arleen Brown, MD, PhD (Community Engagement, LA)
Daniel Dohan (Participant Consent)
Sarah Dry (Laboratory Operations)
Barbara Koenig, PhD (Community Engagement, SF)

#### Steering Committee meets at least quarterly

Principal Investigators
Project Co-Chairs
Operations Committee
5 UC Site Representatives (see below)
Community Representatives: LA and SF

#### **CTSI Administrative Core**

Sally Mead (Chief Administrative Officer) Fabrice Beretta, MBA (Director of Evaluation) TBH, Program Manager

#### Expert Advisory Committee

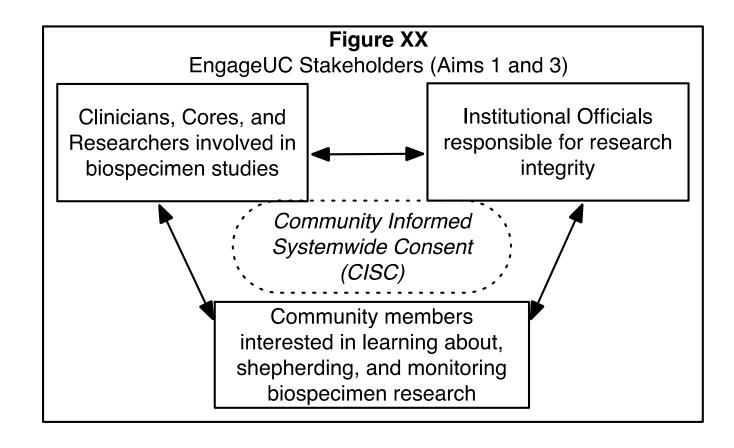
Julie Auger
(Core Facilities)
James G. Kahn, MD, MPH
(Health Economics)
Nariman Nasser
(Participant Recruitment)
John Wilbanks
(Portable Legal Consent)

#### **Steering Committee Site Representatives**

UC Davis: Joshua Miller, PhD, Director, Alzheimer's Disease Center Bank
 UC Irvine: Dan Mercola, MD, PhD, Director, Translational Cancer Biology
 UCLA: Sarah Dry, MD, Director, Translational Pathology Core Lab
 UCSD: David Boyle, Co-Director, Translational Research Technologies Lab
 UCSF: Britt-Marie Ljung, MD, Director, Cancer Center Research Tissue Bank

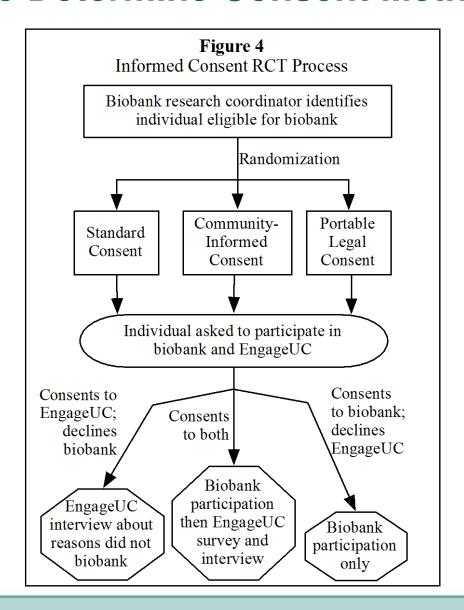


### **Stakeholders**





## **RCT to Determine Consent Method**





# **EngageUC: Project Activities**

#### Aim 1: Stakeholder Engagement (Months: 1-9)

- Convene institutional officers to review/update policies on human subjects in biospecimen research
- Convene biospecimen researchers to propose harmonized procedures
- Create community advisory board (CAB) via
   Deliberative Democracy
- Convene Officers, Researchers and CAB to review biospecimen policies and procedures
- Develop Community
   Informed Systemwide
   Consent (CISC) for
   biospecimen research to be
   evaluated via randomized
   trial

#### Aim 2: RCT of Informed Consent (Months: 10-30)

- Select biospecimen research projects to include in informed consent RCT
- Randomize potential biospecimen participants to receive 1 of 3 options: standard consent, Portable Legal Consent, or Community Informed Systemwide Consent (CISC; Aim 1)\*
- Compare consent quality, trust in research, reasons for accepting or declining, and enrollment rate
- Examine clinician/staff preferences using qualitative interview

#### Aim 3: Policy Translation (Months 30-36)

- Convene IO's, Researchers, and CAB to review RCT results
- Based on Aim 2
   results, develop
   harmonized policies
   for outpatient
   biospecimen
   research
- Devise plan to implement harmonized policies
- Establish system to evaluate and improve UC biospecimen research processes that includes a permanent CAB



# **EngageUC: Timeline & Milestones**

	Project Month	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36
Aim 1	1a – IOs	xxx	xxx	XXX									
	1b – Biobankers	xxx	xxx	xxx									
	1c – Community	xxx	xxx	xxx									
Aim 2	Consent RCT				xxx	xxx	xxx	xxx	xxx	xxx	xxx		
Aim 3	Xlate into Policy										xxx	xxx	xxx
Milestones (project month in parentheses)		* IO & biobanker meetings (2,4,6) * Community meetings SF (7) & LA (8) * CISC & CAB created (9)			* Select campus biobanks for inclusion in RCT (10) * Train EngageUC RAs to conduct RCT (11) * EngageUC RA's in the field (12) * 50% data collected (20); 100% data collected (28) * Analysis complete & results to Steering Committee (30)							* Stakeholders convened (30) * Policies selected (34) * Implementa- tion begun(36)	



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