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EngageUC

*Engaging University of California
Stakeholders for Biorepository
Research*

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September 14, 2012

EngageUC: Engaging University of California
Stakeholders for Biorepository Research



UCLA Health System

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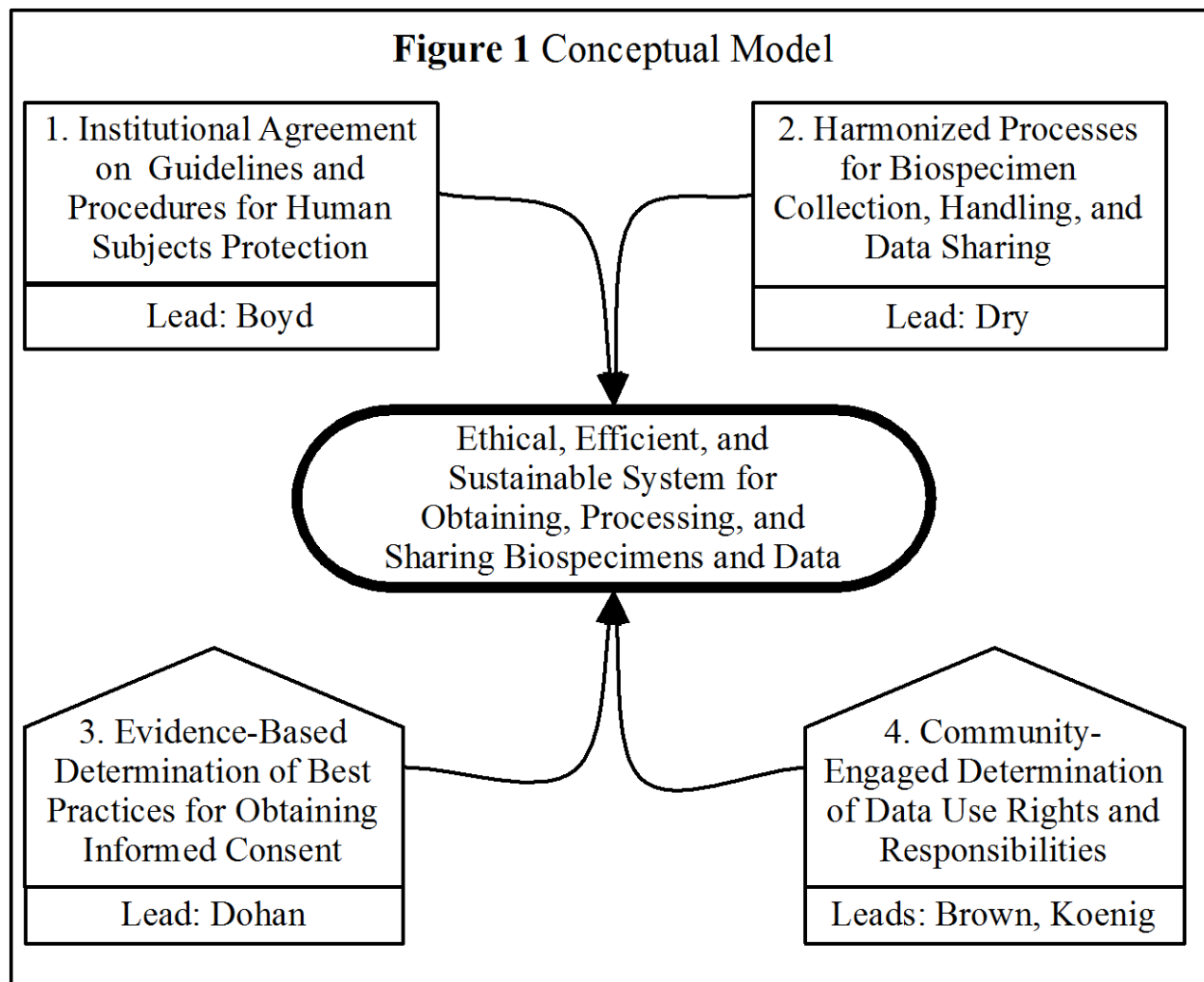
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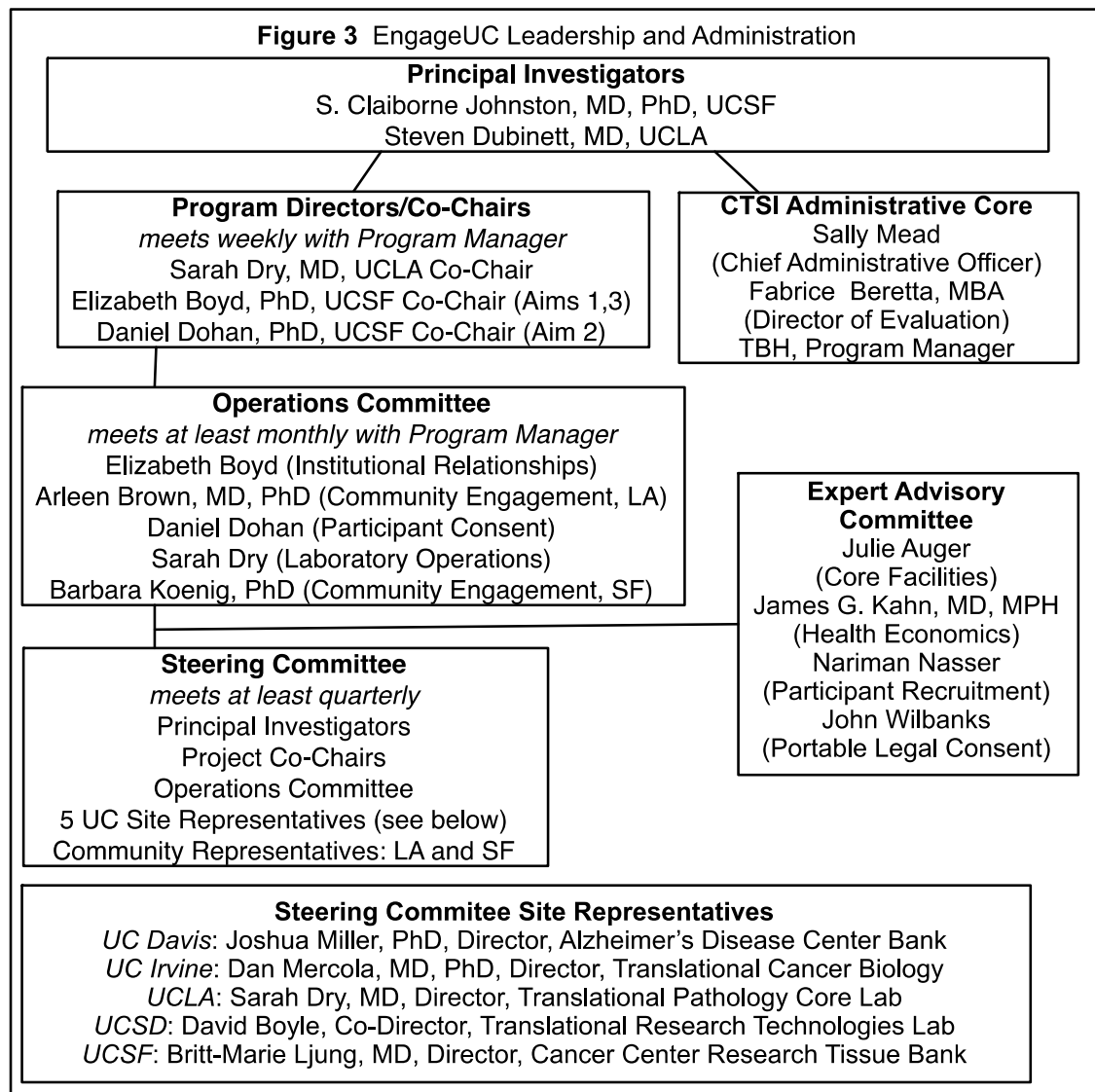
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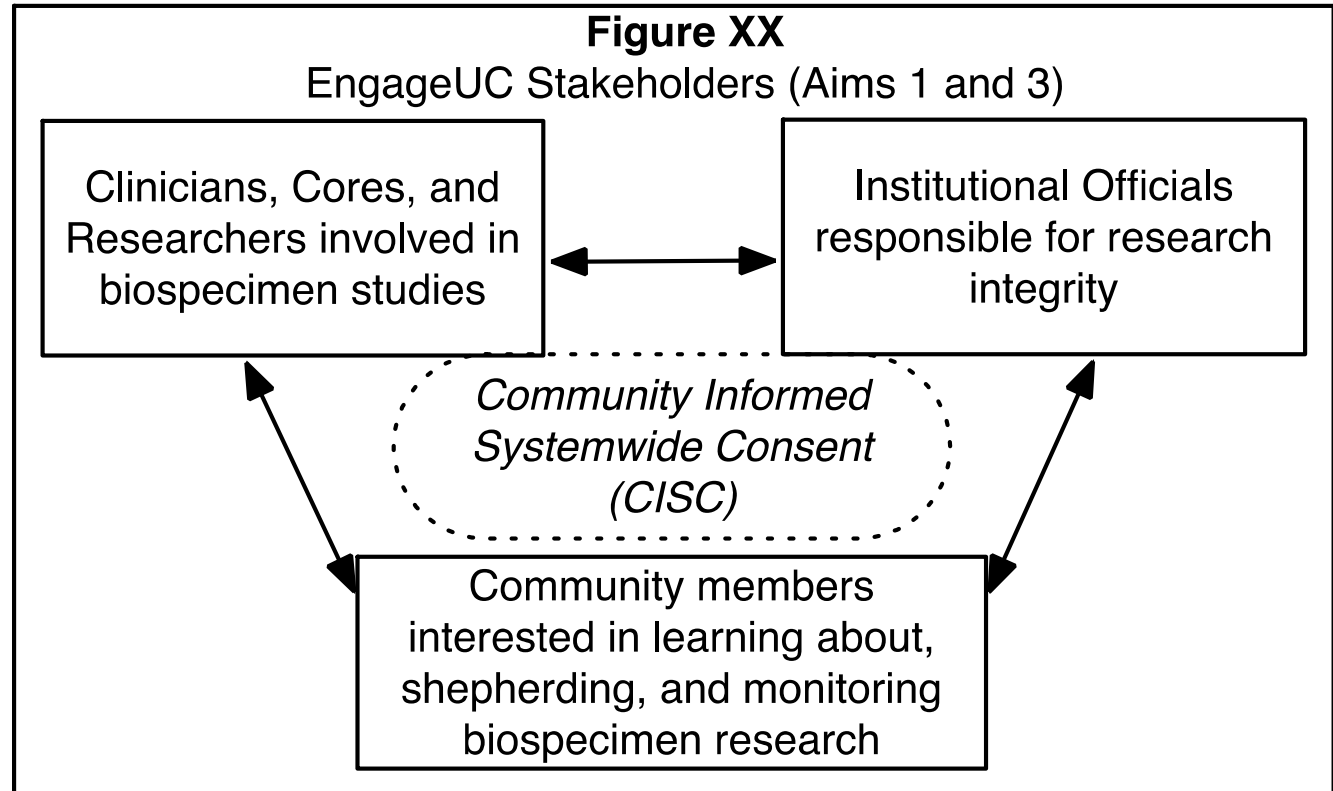
Efficient, Ethical, and Sustainable System for Obtaining Biospecimens and Data



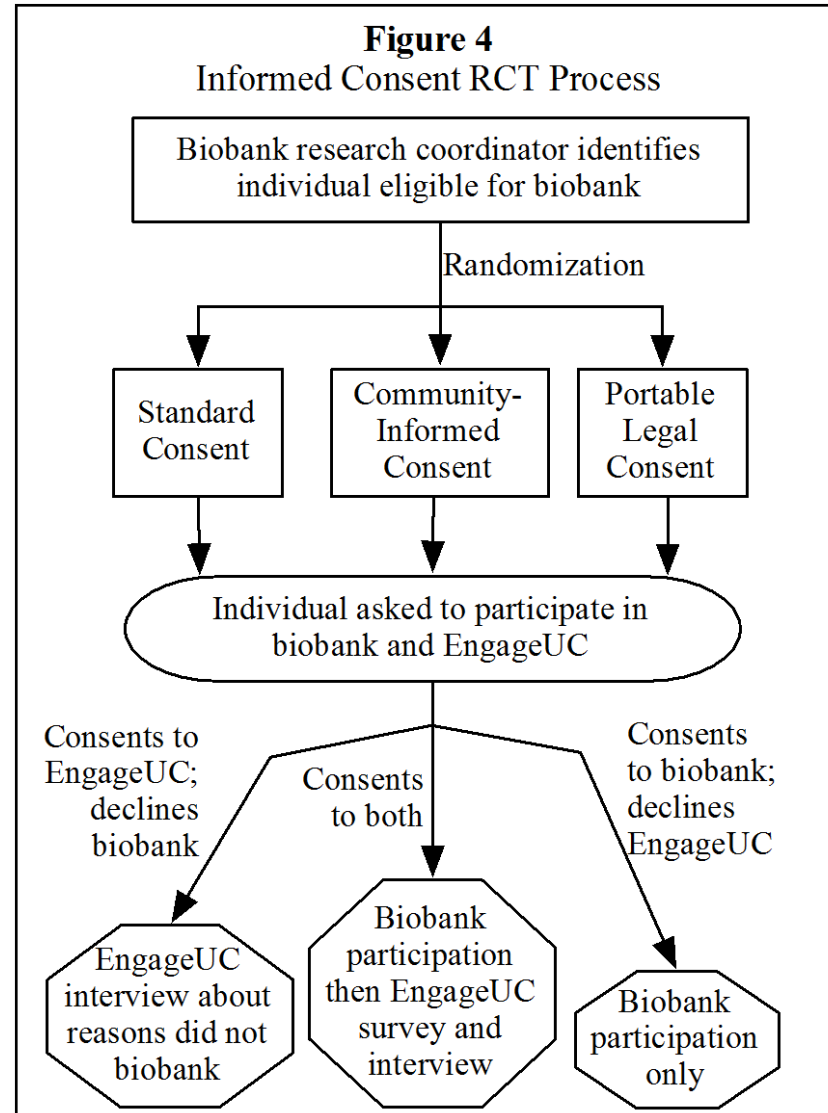
Organization



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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