



HHS Public Access

Author manuscript

Clin Transl Sci. Author manuscript; available in PMC 2016 August 01.

Published in final edited form as:

Clin Transl Sci. 2015 August ; 8(4): 362–366. doi:10.1111/cts.12259.

EngageUC: Developing an Efficient and Ethical Approach to Biobanking Research at the University of California

Sarah B. Garrett, Ph.D¹, Barbara A. Koenig, Ph.D², Arleen Brown, MD, Ph.D³, Jen R. Hult, MPH^{1,4}, Elizabeth A. Boyd, Ph.D.⁵, Sarah Dry, MD⁶, Daniel Dohan, Ph.D.¹, and in collaboration with UC BRAID

¹Philip R. Lee Institute for Health Policy Studies, University of California San Francisco

²Departments of Social and Behavioral Sciences and Anthropology, History, and Social Medicine, University of California San Francisco

³Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine at UCLA

⁴Clinical and Translational Science Institute, University of California San Francisco

⁵Department of Medicine and Office of Research and Economic Development, University of California Riverside

⁶Department of Pathology and Laboratory Medicine, David Geffen School of Medicine at UCLA

Abstract

Biorepositories, or biobanks, provide researchers with access to biological samples and associated data in support of translational research. Efficient operation and ethical stewardship of biobanks involves coordinated efforts among multiple stakeholders including researchers who manage and use the repository, institutional officials charged with its oversight, and patients and volunteers who contribute samples and data. As advancements in translational research increasingly involve more data derived from larger numbers of diverse samples, the size and governance challenges facing biorepositories have grown. We describe an approach to developing efficient and ethical biobank governance that includes all major stakeholders. This model provides a pathway for addressing the technical and ethical challenges that must be resolved to ensure biorepositories continue to support translational research.

INTRODUCTION

Biorepositories (or biobanks) contribute to medical discovery by providing researchers with ready access to large numbers of tissue and fluid samples and associated clinical data. In the last decade, academic centers, health systems, industry, and governments have promoted the growth and consolidation of biobanks, as researchers have sought larger numbers of samples from diverse populations. Growth and consolidation of biobanks is part of a broader trend emphasizing the use of “big data” to advance biomedical research and improve health.

Along with growth and consolidation has come a recognition of the technical and ethical challenges in managing and governing biobanks. From a technical perspective, biorepositories have developed in an uncoordinated fashion as researchers and institutions pursued local research opportunities and needs. Collection, storage, analysis, and distribution of samples varies across banks – variation that can create uneven quality and administrative inefficiency, both of which result in needless costs and delays for clinical and translational research.¹ Developing common technical standards for collecting and sharing samples and data has the potential to advance biobanking.²

Biobank governance is also a challenge as practices often focus on statutory compliance rather than the ethical priorities of patients or research volunteers.^{3,4} Current regulations developed in an era when biobank research occurred at a smaller scale, and their application in the current research environment creates uncertainty in ethical arenas such as obtaining consent for unspecified future uses of samples, accessing remnant or legacy samples, linking sample-derived data with medical records, determining when and how to return individual results, and sharing samples and data across institutions and borders.⁵⁻¹¹ Empirical bioethics can provide a foundation to address these issues by illuminating patients' and volunteers' understandings in these domains and exploring how priorities for personal and health privacy are shifting in the age of the internet and big data.

Several domestic and international consortia have convened researcher, institutional, and community stakeholders to discuss the techniques and ethics of larger-scale biobanking, e.g. in the Clinical and Translational Science Award Consortium, eMERGE projects, P3G, and ISBER.¹² Here we contribute to these discussions by outlining the approach of EngageUC, which seeks to establish an approach to harmonize biobanking policies and practices across five University of California (UC) campuses. A UC biorepository could potentially include samples from the estimated 13 million ethnically diverse Californians who have clinical or research relationships with UC.

EngageUC builds on five existing NIH Clinical & Translational Science Award (CTSA) centers and the University of California Biomedical Research Acceleration, Integration & Development (UC BRAID) consortium, and leverages the system-wide policy-making capacity of the UC Office of the President (UCOP). The opportunity to leverage BRAID and UCOP make EngageUC unique, but we argue that EngageUC's strategy to accelerate research advances previous work and is generalizable. This strategy builds on Kingdon's theories of public policy change and has two central features. First, to address current challenges facing biobankers – and to anticipate future challenges – EngageUC seeks to develop new policy that is evidence-based. Second, to create a favorable atmosphere for change, EngageUC engages and convenes a wide range of stakeholders, including researchers who build, use, and maintain biobanks; administrators charged with regulation and oversight; and members of the public whose blood, tissue, medical records, and other data are stored and shared.

METHODS

EngageUC employs a multi-method design that integrates evidence about stakeholders' perspectives and operational best-practices to create a harmonized and single platform for contemporary biorepository research.

Sites

The sites for EngageUC are the five UC medical center campuses (UC Davis, UC Irvine, UC Los Angeles, UC San Diego, and UC San Francisco). The five UC centers are geographically and administratively distinct and have many distinct practices and policies related to research and biorepositories. The campuses employ hundreds of researchers and possess clinical data from approximately 13 million current and recent patients. These patients are largely drawn from California's population of 38 million, which is notable for its diversity with respect to race and ethnicity, nativity and geographical ancestry, socioeconomic status and educational attainment, languages spoken and health literacy, and rural and urban residence. EngageUC also includes the University of California Office of the President (UCOP), which provides central administration for the UC system, and the UC BRAID consortium. UC BRAID is a collaborative network of leaders, faculty, administrators, and UCOP partners focused on advancing clinical and translational research infrastructure to accelerate health improvement. Established in 2010, BRAID has developed UC-wide governance and infrastructure to support clinical and translational research, including IRB reliance, contracting support, and the UC Research eXchange (ReX) informatics infrastructure that provides researchers secure access to 11.8 million patient records across the UC health system. UC BRAID also includes a biobanking workgroup, which has been closely integrated with EngageUC. UCOP is funded by UCOP and the five medical center campuses and governed by an Executive Committee composed of the Principal Investigators of the five UC CTSA centers. Each PI has a senior university leadership position and is thus integrated into university administration. EngageUC has worked closely with the UC BRAID Executive Committee and the Biobanking and Regulatory (IRB) workgroups.

RESULTS

EngageUC has three distinct components: 1. engaging stakeholders to develop a common platform of biobank governance; 2. developing new evidence about best practices for consenting Californians who participate in biobanking as research subjects; and 3. translating and integrating guidance on governance and evidence about consenting into UC-wide policy. See Table 1 for an overview of the stakeholders, their roles vis-à-vis UC biobanking, and the ways in which they were engaged by this project.

Engaging Stakeholders: Public Deliberative Community Engagement

Ordinary Californians are the ultimate stakeholders in the public University of California system and its research and clinical activities. Therefore, EngageUC places a premium on understanding public perspectives on the role, practices, and governance of UC biobanks. Engaging the public in discussions and decisions about biobanking is crucial because the

public's interests and viewpoints may differ from those of the expert stakeholders in research institutions.¹³ However, directly soliciting public opinion, e.g. via surveys or focus groups, may produce sub-optimal results because few members of the public have the specialized knowledge necessary to provide meaningful input on complex questions surrounding biobank governance. Over the last two decades, techniques for deliberative democracy have been developed that address the challenge of eliciting meaningful engagement by ordinary members of the public on technical or specialized issues facing governments. EngageUC adopted Deliberative Community Engagement (DCE), which has been successful in previous projects focused on biobanking. In DCE, 20–30 individuals are purposefully selected to represent a particular population – in this case, the population of California. These representatives are then educated so that they can serve as informed deliberants to discuss, debate, develop, and potentially achieve consensus on specific recommendations about biobanking practice and governance. EngageUC convened two four-day face-to-face deliberations with two separate groups of representative deliberants: one in Southern California (Los Angeles, June, 2013) and one in Northern California (San Francisco, September/October, 2013).

Identifying and Educating Deliberants—To recruit a representative group of deliberants, EngageUC partnered with the California Health Interview Survey (CHIS), a UCLA-based research program that has surveyed large, systematic samples of Californians on a variety of health-related issues since 2001. EngageUC opted to recruit potential deliberants from CHIS' existing database of Californians who had already completed a CHIS survey and had indicated a willingness to be contacted for future research. We sought 35 individuals for each site, assuming that 25 would ultimately attend each event. EngageUC investigators worked with CHIS to develop purposeful sampling frames with separate strata and recruitment targets based on sex, age, education, and race/ethnicity. Recruitment in Los Angeles included an additional focus on Native Americans and monolingual Spanish-speakers; the San Francisco event focused on recruiting Asian-Americans.^{14,15} Fifty-one deliberants were ultimately recruited. In Los Angeles, 8 of the 26 deliberants were monolingual Spanish speakers, and the LA DCE occurred with simultaneous English-Spanish translation. All 25 San Francisco deliberants were fluent in English.

To facilitate deliberant education, the EngageUC team developed a briefing book that was made available as text and voice recording (for low-literacy participants) in English and Spanish. The briefing book described how biorepositories operate, how they are governed (including sample and data ownership under California law, NIH and other federal regulation of genomic data, and the operations of IRBs), and presented differing perspectives on challenges facing biobanks (e.g. the need for larger numbers of samples to support contemporary research, issues surrounding genetic privacy and re-identification, dilemmas such as return of incidental findings, and case studies of ethical dilemmas including the Henrietta Lacks and Havasupai tribe cases). The briefing book was made available to deliberants three weeks before the first DCE meeting. During the first day of the in-person DCE, deliberants engaged experts in biobank research, operations, and governance – experts drawn from UC faculty and administration, health systems, and patient advocacy

organizations. Experts presented prepared remarks and addressed deliberant questions. Experienced facilitators guided panel discussions during which deliberants explored issues of particular interest or concern. In Los Angeles, one presentation was conducted in Spanish with simultaneous translation to English.

Deliberation and Voting—During the next two days of the DCE at each site, a team of experienced facilitators met with the deliberants to discuss issues raised by the EngageUC team and by the deliberants themselves about biobanking practice and governance. The format for these deliberations involved: a brief large-group meeting where facilitators introduced a particular theme for deliberation, e.g. sharing samples and data; a small group meeting of 8–9 deliberants lasting 60–90 minutes to discuss the issue; and a large group session during which each small group shared and discussed their ideas and conclusions. For example, the opening session focused on hopes and concerns for biobanking in California. In small groups, deliberants jotted ideas on Post-It notes and then reviewed and discussed among themselves. At the end of each small group, deliberants summarized their discussion for presentation during the large group meeting that followed. In Los Angeles, one small group was conducted in Spanish, and all large group sessions were simultaneously translated in English and Spanish. To document the deliberation, all sessions were audio-recorded and EngageUC team members observed and took detailed ethnographic field notes during each session.

After each day of deliberation, the EngageUC and facilitation teams met to review the day's discussion. The teams identified areas of consensus and debate and then framed these areas as recommendations to be voted upon, e.g. "UC biobanks should include oversight by a group of ordinary Californians." To the extent possible, the language used by deliberants themselves was preserved. During the final day of the DCE, the lead facilitator reviewed these recommendations with the deliberants. Deliberants discussed and refined the language of each recommendation and then used an audience response system to anonymously vote on whether to endorse its final wording. Following each vote, a facilitator invited deliberants to discuss the reasoning behind their vote. All propositions, discussions, votes, and justifications for votes were recorded for later analysis and became an important product of the DCE.^{16–18}

Engaging Stakeholders: UC Biobankers

Even before the DCE took place, UC BRAID established infrastructure for identifying clinical and translation needs across the five UC medical center campuses. In 2012, the BRAID biobanking group brought together biorepository leaders at the five campuses to review policies and recommend best practices for biorepository research at UC, and to create a biorepository network across the five campuses. The biobank stakeholders included pathologists, research scientists, and biorepository staff members. EngageUC provided additional resources, foci, and inputs for this group, and has communicated continuously with BRAID throughout the course of the project

The products of the biobanking group engagement were documents describing standard operating practices (SOPs) and professional governance. The biobankers achieved

consensus to adopt SOPs based on national (NIH and CAP) and international (ISBER) standards. A model for professional governance proved more challenging. The group was divided about whether to create a “path to excellence” for all biobanks or to focus only on those biorepositories at each campus which were interested in becoming “UC-recognized” biobanks. This discussion reflects the reality that each UC campus, like academic centers across the US, may have hundreds of biobanks. In the end, the group decided the “path to excellence” approach was preferable as it would create a formal approach to help all biobanks improve their operations and standards. The group agreed that there would need to be incentives for biobanks to participate; possible incentives included education about relevant standards, assistance with SOPs, help with CAP accreditation preparation, and institutional funding. Currently, the group is developing a research survey to understand what types of samples and associated data are most desired by UC researchers, so that a pilot test of a UC biorepository network can occur.

Engaging Stakeholders: UC Institutional Officials

The final stakeholder group are UC administrators (IRB directors, Institutional Officials, research Chancellors at each campus and officials at UCOP) who oversee donor consent and biorepository operations. The goal for institutional official engagement was to understand current practices and needs for oversight and to explore whether these officials might consider implementation of system-wide practices, for example a universal form for obtaining donor consent.

In Summer 2013, meetings with IRB directors and their affiliates were convened at each campus to directly engage those who are responsible for the oversight of research involving biospecimens and for establishing campus policies and procedures for biobanks and researchers. These group interviews focused on concerns over the continued uncoordinated activities of campus biobanks, the need for consistent and clear processes for both clinicians collecting samples as well as faculty who desire to conduct research with biospecimens, the need to develop consent documents that clearly communicate the research benefits and risks associated with biospecimen donation, and the challenge of implementing policy changes across the system. One example of these discussions: IRB directors endorsed their willingness to undertake development of UC-wide standard consent materials. Broader themes related to biobank governance will be addressed during the translational phase of EngageUC (see below).

Best Practices for Consent

UC patients and research volunteers asked to contribute samples are important stakeholders in biobanking, and obtaining their meaningful informed consent for donation should follow evidence-based best practices. EngageUC contributes to this evidence base by building on the results of the DCE to design a randomized trial of different procedures for obtaining informed consent for UC clinics and research biobanks. The EngageUC trial includes three arms: IRB-approved methods currently used in the UC system (arm 1), versus a simplified Community-Informed System wide Consent (CISC) the team developed based on DCE interest in a simpler consent process (arm 2), versus the combination of CISC with an educational video about biobanking, which responds to the DCE consensus that multi-media

approaches for educating potential biobank contributors is preferred to relying on text alone (arm 3).

The EngageUC trial of informed consent practices partners with outpatient clinics and research sites that are already conducting specimen collection. Randomization is on a per-site basis to guard against contamination that would occur if site staff were asked to present different patients with different consent forms. The outcomes to be assessed include: 1. the proportion of patients/volunteers who consent to biobank participation; 2. Patient biobank knowledge and trust in biomedical researchers as measured by two short surveys; and 3. qualitative interviews about the consent process with patients/volunteers (about the informed consent experience and reasons for consenting or declining) and with clinic staff (about perceptions of effectiveness and feasibility of each arm). While other studies have investigated these questions using simulated consent scenarios,^{19,20} EngageUC seeks to provide actionable evidence about consent practices through the use of a randomized design in a naturalistic setting.^{21–23}

Translation into Practice

In BRAID and elsewhere, UC stakeholders have expressed support for a coordinated UC biobank effort. Preliminary results from the DCE suggest ordinary Californians also support UC biobanking and see value in developing UC's capacity for biorepository research. The EngageUC translational effort seeks to transform these positive intentions into actual UC policy that reflects stakeholder interests and incorporates best practices for consent. To that end, EngageUC is sponsoring a workshop at which selected deliberants, UC biobankers, and campus and UCOP administrators will meet and develop a roadmap for creating UC biobanking policies across the five UC medical center campuses.

We anticipate key challenges in translating stakeholder perspectives and consent best-practices into UC-wide use include the following: How should system-wide biobank governance be coordinated with campus-based governance? Should UC strive for policy harmonization or should it encourage campus-specific innovation? What are the next steps for engaging the public in the development of a biobank governance framework? The roadmap meeting will provide a forum for stakeholders to discuss their interests and concerns with one another with the goal of finding agreement where possible and identifying conflicts that cannot be resolved.

DISCUSSION

EngageUC adds to a growing literature about best practices for biorepositories to support contemporary biomedical research. Translational research increasingly requires large numbers of high-quality specimens linked to clinical data. Specimens collected, prepared, analyzed, and linked to clinical records using high-quality procedures and transparent governance advance science by ensuring researchers can reliably interpret findings derived from large study populations. When researchers are uncertain of procedures used to produce data, they cannot reliably interpret their own analyses. When data are poorly governed, researchers cannot confidently create the large datasets they need. EngageUC outlines an

approach to address the ethical and policy challenges in creating biorepositories that are high quality and well governed.

As more and larger national and regional biobanks have been established,^{24–26} research on these institutions and their practices has followed. Several scholars have conducted studies that feature individual aspects of the research we present here. These include deliberative community engagement activities;^{16,18} the evaluation of different consent materials for potential bio-bank donors;^{22,23,27} and deliberations among geneticists, biobank leaders and other experts regarding practices and policies of large-scale biobanking.²⁸

Additionally, scholars have made dedicated attempts to create a dialog between decision-makers and the public. For example, in a 2009 Vancouver, Canada, DCE, O’Doherty et al (2012) collaborated with senior bio-library cancer registry personnel from the provincial biobank to create a workbook that would guide lay deliberants to structure their discussions and recommendations so as to be “both politically legitimate and practically relevant.”^{18,29} The Mayo Clinic “formalized and extended” early deliberation-based interactions between the public and decision-makers by later recruiting participants to serve on advisory boards for its biobank and the affiliated Rochester Epidemiology Project.^{30,31} Other efforts to bring biobanking decision-makers together with the public and other stakeholders are found domestically and abroad as well.^{32,33}

While other projects have sought to improve operations of a single institution, EngageUC aims to improve biobanking system-wide—something that requires new policy. Kingdon and Thurber (1984) argue that creating policy is a tri-fold challenge: first, a problem must be identified; second, a solution must be developed; and third political will must be mustered to implement change.³⁴ Policy change occurs only when the three “streams” of problem, policy, and politics converge.

For UC biobanks, governance is a central element of the problem stream. Academic silos make it difficult for researchers to generate large datasets, and weak institutional governance makes it difficult to break down silos. Governance must be not only be institutionally potent but also be trustworthy in the eyes of the patients and public who contribute samples and data.

The UC BRAID biobanking initiative developed one element of the policy stream: standard operating procedures (SOP) that all UC biobanks can follow. EngageUC’s empirical work seeks to create additional elements of the policy stream, including evidence about how to establish governance structures that ordinary Californians find trustworthy as well as a rigorous examination of which procedures produce true informed consent from patients and research volunteers.

Engagement is key for the political stream. EngageUC repeatedly engages all biobanking stakeholders. Repeated engagement provides opportunities to remind academic stakeholders from campus and central administration that ordinary Californians expect research advancements from UC. Public interest and scrutiny can help provide the political will to overcome disciplinary silos and institutional inertia.

CONCLUSION

Biobanks play a central role in medical research, and the scientific community has an opportunity and obligation to create operational and governance frameworks that ensure biobanks facilitate research rather than encumber it. No two biobanks are exactly alike. We do not argue that the specific activities employed by EngageUC will be helpful or appropriate in all circumstances. But our strategic approach – which emphasizes evidence-based solutions and iterative stakeholder engagement, including of the general public – may offer a blueprint for developing efficient biobank operations and trustworthy governance.

Acknowledgment

We gratefully acknowledge the support, advice, and input from members of the UC BRAID Executive Committee (Lars Berglund, Steven Dubinett, Gary Firestein, Deborah Grady, and Daniel Mercola) as well as S. Claiborne Johnston, Rachael Sak, Giuseppe Cavaleri, Holly Longstaff, and Michael Burgess.

Engaging University of California Stakeholders for Biorespository Research is funded by NIH UL1 TR000004-07S2 (National Center for Advancing Translational Sciences).

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Table 1

Overview of EngageUC Stakeholders

Stakeholder Group	Role in UC Biobanking	Mode of Engagement
Ordinary Californians (Including UC patients and research volunteers)	Current or potential donors; Potential beneficiaries of biobank research discoveries	* DCE event
		* Consenting trial subjects
		* Stakeholder workshop
Biobankers	Manage biobanks; implement policies and procedures related to sample and data handling, oversight, and sharing	* BRAID working group
		* Stakeholder workshop
Institutional officials (including IRB directors)	Regulatory oversight of biobank policies and operations	* Focus groups & interviews
		* Stakeholder workshop
UC Researchers	* Facilitate sample donation	* Consenting trial subjects
	* End-users of samples and data	* Stakeholder workshop
UC Leaders (UCOP and individual UC campuses)	Fund and oversee biobank operations	* BRAID executive committee
		* Stakeholder workshop