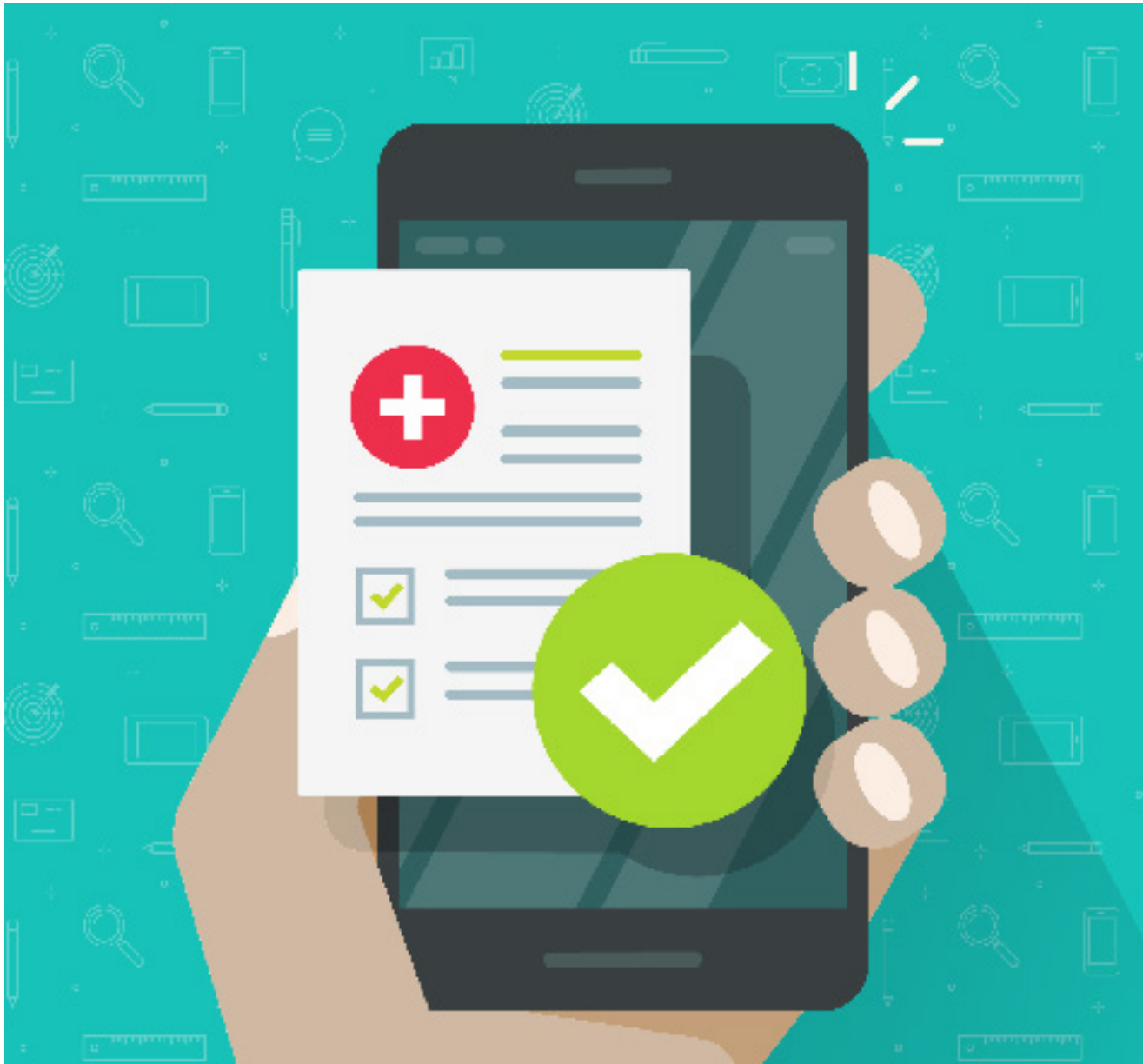


Modernizing Consent to Advance Health and Equity

A NATIONAL SURVEY OF KEY TECHNOLOGIES, LEGAL ISSUES AND PROMISING PRACTICES

EXECUTIVE SUMMARY



Stewards of Change
INSTITUTE

Modernizing Consent to Advance Health and Equity

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We're especially grateful to the dozens of subject matter experts, technologists, government officials and other professionals nationwide who volunteered their time to conduct the work involved. A list of participants in this project is in Appendix C on Page 69, and the organizational logos of key contributors appear on Page 6.



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Executive Summary

In early 2021, the Stewards of Change Institute (SOCi) held an online symposium, in partnership with the Stanford University Center for Population Health Sciences, that culminated a yearlong, highly collaborative initiative titled “The [National Action Agenda](#) to Advance Upstream Social Determinants and Health Equity” (NAA).

Several recommendations grew out of that event. The primary one was to accelerate health-related progress by modernizing the archaic processes by which individuals (patients, clients, etc.) provide informed consent for their personal data to be shared across programs, systems and domains.

SOCI [launched several projects](#) to further that objective, including a scan of key efforts in the U.S. that aim to improve consent, as well as to explore the legal and technical challenges of enabling consent-driven data sharing across healthcare and human services. The results of that scan make up the bulk of this report. We also interviewed about two dozen subject-matter experts, reviewed relevant resources, and received ongoing information and insights from the dozens of additional experts who worked with us. This national scan offers the first examination/aggregation

of consent-related activities in a decade. We undertook the project because we believe there’s an urgency to obtaining and utilizing this accumulated learning for reasons including:

- The pandemic’s spotlight on the need to improve information sharing and on the racial and socioeconomic disparities impeding better healthcare for too many people.
- A growing focus on the importance of the Social Determinants of Health and Well-Being (SDOH), without a clear roadmap or systems-level processes for addressing them.
- The immediate opportunity to apply, test and scale what we learn – with the goal of instigating and implementing structural change – beginning with the federally funded Integrated Care for Kids (InCK) sites in New York and New Jersey, which have agreed to be SOCi’s implementation partners on this work.

The content in this report comes primarily from health-care-related domains, because those are where issues related to consent currently receive the most attention and

where, generally speaking, the most progress on modernizing consent processes is being made. That said, our “target audience” is not solely healthcare institutions and systems.

.....
‘As we’re moving into this next generation of adding more complexity to the data sources . . . it is incumbent on us to really step up the game and make sure that we have true informed consent and that we have an appreciation for how people can be educated about who is seeing their data and when. . . . We’re going to have to sort out a way to create an interoperability between public health and social care systems in particular.’

*– Karen DeSalvo, MD, MPH, Chief Health Officer,
and former ONC National Coordinator
speaking at the HL7 35th Annual Plenary, September 20, 2021*

.....

Rather, our intent is to 1) provide information and insights for non-healthcare professionals to advance their consent processes; 2) spotlight the essential need to include and build trust with People with Lived Expertise in all phases of this work; 3) advance the creation and adoption of an open-source, replicable and customizable solution for consent-related efforts; and 4) accelerate understanding of the importance of cross-sector data sharing among all of those contributing to people’s health and well-being (e.g., healthcare, human/social services, behavioral health, education and other SDOH factors) to increase development and implementation of processes to further that aim.

In conducting its scan, SOCI and its partners identified numerous governmental and business-sector organizations engaging in promising practices. For the purposes of this report, that means they have created, are creating or are now using digitized/computable consent systems (as opposed to paper-based ones) that hold the promise of significantly enhancing operational efficiency and effectiveness; giving individuals more-granular control over their data; demonstrably contributing to progress toward greater health equity and better outcomes; furthering cross-domain partnerships and/or better care coordination that addresses SDOH; and containing approaches, technologies and/or additional elements from which others can learn to improve their own efforts.

It is important to emphasize that the systems, projects and other efforts described in our full report are not the only ones devising and implementing promising practices; rather, they are examples of such work, which we’ve sorted into four “categories:” Health Information Exchanges (HIE), Electronic Physical and Behavioral Health Record Systems (EHR), Community Referral Services (CRS), and Community Information Exchanges (CIE). One additional category, Industry and Governmental Initiatives, focuses on examples of federal or industry-supported efforts that have highly applicable learning related to consent.

Finally, we want to clearly state from the start that we recognize there are ethical and trust issues, privacy concerns, multi-jurisdictional laws and legal decisions, potential risks and even possible harms that must be factored into any work related to informed consent, and to the sharing of personal/ private information more broadly. The overarching goal of improving health, well-being and equity is undermined if those considerations aren’t top of mind at every step, from planning to implementation.

Overview and Background

One of the most vexing impediments to maintaining privacy, while improving care delivery across health and social services through programs, is the lack of a coherent national framework or standardized digital means to enable and track approval by individuals to share their personal data within and across the multiple programs, systems and domains (e.g., education, housing, etc.) that contribute to everyone’s health and well-being. Indeed, most processes for consenting to share information today are slow, onerous and hard to monitor or manage, largely because they’re conducted in silos and are paper-based.

As a result, every organization must determine for itself how to manage the many factors involved, a reality that hampers efforts to achieve greater uniformity and otherwise drive innovation and progress. In addition, patients currently wishing not to share some of their records sometimes must either have their privacy compromised and share everything, or have to choose to share nothing and potentially receive worse services because the care team doesn’t have the individual’s full clinical and social context.

The bottom line is that, even when consent is documented, significant issues complicate the sharing process. The complexities involved include but aren’t limited to:

Lack of consent “granularity.” Consent is usually applied generally to an entire record, without empowering individuals to specify which data can be provided to whom or for what purposes. Lack of uniformity. There is no uniform definition of “consent,” nor is there broad acceptance of what data, organizations and users are impacted by a specific consent.

Lack of communication. The many domains that can/should share data have different systems and procedures in place that cannot “talk” to each other.

Lack of discoverability. With personal information distributed so widely, it is difficult for an individual to know what systems have their sensitive data or how to manage it.

Lack of trust and understanding. Perhaps most importantly, there is often a lack of trust -- especially among PwLE -- relating to service providers, as well as a lack of understanding of their consent- and privacy-related rights.

Enabling and accelerating the secure, digitized/computable exchange of personal health and social data could help healthcare and social services providers improve their assessments of patient/client risk and develop more-comprehensive, coordinated care plans.

Primary Findings and Learnings

The following are some of the key things we discovered, learned and discerned during the course of our scan, notably including from the interviews we conducted. The full report elaborates on all these points and others.

Identity management is a prerequisite for informed consent. If an individual’s correct, verified identity is not determined and managed, then core issues such as privacy, data-sharing and informed provider services cannot be adequately, ethically addressed.

The development and implementation of effective consent procedures and architectures are hindered by: regulations (or the interpretation of them); a lack of understanding in some organizations of privacy rights and a tendency to interpret underlying regulations too restrictively; and “all or nothing” practices.

The participation of “People with Lived Expertise” needs to be meaningfully incorporated into current and future efforts relating to consent (as well as other efforts affecting them) to assure that their input, insights and influence are integral to the planning, decision-making, implementation and other aspects of this work.

The US suffers from a patchwork of uncoordinated federal and state laws that address privacy and consent issues in either healthcare or non-healthcare domains. Indeed, they often do not align with each other or lack clarity about how they interact, thereby leaving gaps and causing confusion even on fundamental questions.

There are no established structures for addressing and resolving multi-domain privacy and consent issues/problems/challenges. Instead, they are currently dealt with in a piecemeal fashion, usually within the affected domain and with resolutions that primarily or exclusively impact only that domain.

There is no system, process or repository that enables a patient/client, provider, care-giver or any other professional/organization to find an informed-consent directive given by an individual, irrespective of where that person lives (or lived) or in what domain/context the consent was provided. That reality undermines even the most ambitious current efforts to improve services, processes and outcomes.

Outside of Health Information Exchanges (HIEs) and Community Information Exchanges (CIEs), consent standards have not been widely adopted to share and enforce consent declarations across IT systems. Instead, proprietary consent functionality enables collection, revocation and enforcement in siloed systems.

A lack of maturity of human service data standards could impede granular data sharing. Nevertheless, existing open-source technology could serve as the foundation for a Consent Service Utility, such as one being developed by SOCI, which would offer significant promise for enabling people to have greater control over their data.

Education and investments are needed for ongoing learning about the laws, regulations, policies, data and technologies that have an impact on informed consent. We stress “ongoing” because many of those things differ from institution to institution and state to state, and they are changing rapidly.



Voices from the Community

Because we steadfastly believe community engagement and the remediation of systemic bias and inequity are always vital, we interviewed members of the Bronx Community Research Review Board about this report and some of the issues it addresses. The BxCRRB’s mission is to “eradicate health inequities” in marginalized communities in the Bronx. We chose the Bronx because it is the site of one of SOCI’s partners in its consent work, the federally funded Integrated Care for Kids project.

These interviews constitute a first step toward far greater involvement by “people with lived expertise” in any planning or action steps we take as a result of what we’ve learned in conducting this project.

.....
‘There’s no such thing as a single-issue struggle because we do not live single-issue lives,’ said one interviewee.
.....

The interviewees agreed that three keys to making progress on consent – and many other issues – are having a broad context, building trust and understanding the value of relationships. The full report elaborates on the following key points BxCRRB members made relating to consent:

Consent isn’t just about the individual asked to provide it.

Though it is often treated as a process affecting just a person filling out a form, that individual may have family with whom they want to discuss whatever they are being asked to consent to – and who could also be significantly impacted. That means the individual needs time to go home, think and talk, rather than having to immediately sign on the dotted line. In addition, the process should take into account the need to build relationships with doctors and other service providers, so it’s about trust and not just information to complete a transaction.

It’s a big problem if consent moves primarily to apps, especially for people in disadvantaged communities who might not own smartphones, don’t have adequate wireless services and/or lack technical knowledge. Paper may be preferable for them, perhaps most significantly so they can take the forms home, where they can talk to others and think about the benefits and risks of sharing their data. And, whether the consent forms are on paper or on a device, it’s critical that they be written in language that is easily understandable and as devoid as possible of specialized (ex., legal or technical) wording or jargon.

.....
Added another: ‘It should be about relationship, relationality, relationality. . . . Data is not going to matter in the absence of remedial harm and shaping relationships.’
.....

Professionals don’t always understand the implications and consequences of their requests for consent. Rather, they view the process as purely transactional – you sign here now and then we’ll provide a treatment or a service. The patient/client, however, may reasonably wonder how and with whom their information will be shared (perhaps a service provider who harbors a racial bias?) as well as what the consequences may be (ex., if a years-old court record is shared with a child welfare worker). So the process needs to include thoughtful conversations to ensure the individual is genuinely informed.

There’s an inherent power imbalance between the people giving or denying consent – especially in marginalized communities – and the professionals providing social services or medical care. That means patients/clients can feel intimidated into approving the sharing of their personal information or believe (often rightly) that they have to do so to receive the treatment or service they require. Consent-related processes need to recognize this reality and mitigate its potentially negative impact, including by providing information to ensure that recipients clearly understand the risks as well as the benefits.

.....
And this third comment: ‘If I can’t have an interactive relationship, I don’t want it.’
.....

A history of racism and socioeconomic disparities means the perspective of individuals being asked to provide their approval isn’t shaped only by the questions relating to consent and information sharing per se. Rather, it’s also based on personal and historical experience. So, for example, will they believe that all the people they’re dealing with – or the ones receiving their data – have their best interests at heart? Will that information be properly used? Who will the real beneficiary be, the patient/client or the institutions requesting the consent and participating in the sharing?

Recommendations and Next Steps

A more-complete list, with elaboration on each item, is in the Recommendations section of the full report:

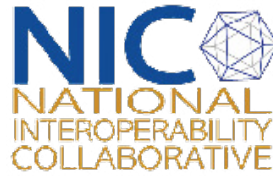
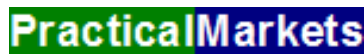
1. The dozens of participants in this project should collaboratively plan and carry out a series of activities in 2021 and 2022 (and beyond) to advance the information, insights and learnings reflected in this report.
2. Remediating socioeconomic and racial disparities, as well as building trust and furthering health equity, should be built into the framework of all the activities outlined in these recommendations.
3. People with lived expertise should be incorporated into all aspects of consent-related efforts to increasingly give them genuine agency over the decisions and actions that impact them most.
4. The ONC and other federal agencies, pointedly including ones that focus on SDOH and not just healthcare, should

launch regular meetings on consent and data sharing.

5. SOCI and its collaborators should continue development of an open-source, standards-compliant Consent Service Utility (CSU) as a key part of implementing the guidance in this report.
6. A symposium should be planned, organized and staged in mid-2022 to share the ideas and insights reflected in this report, as well as additional ones generated by the activities above.
7. A widely marketed webinar “learning series” should be organized to begin as soon as possible after publication of this report, and to continue at least until the 2022 symposium.
8. The InCK sites should be used as a national model for developing, testing and implementing the modernization of consent practices across programs, systems and domains.



Thanks to Our Participants



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