Stewards of Change
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Catalyzing Whole-Person Care: Consent-to-Share is the Key

Insights, Next Steps and a Roadmap

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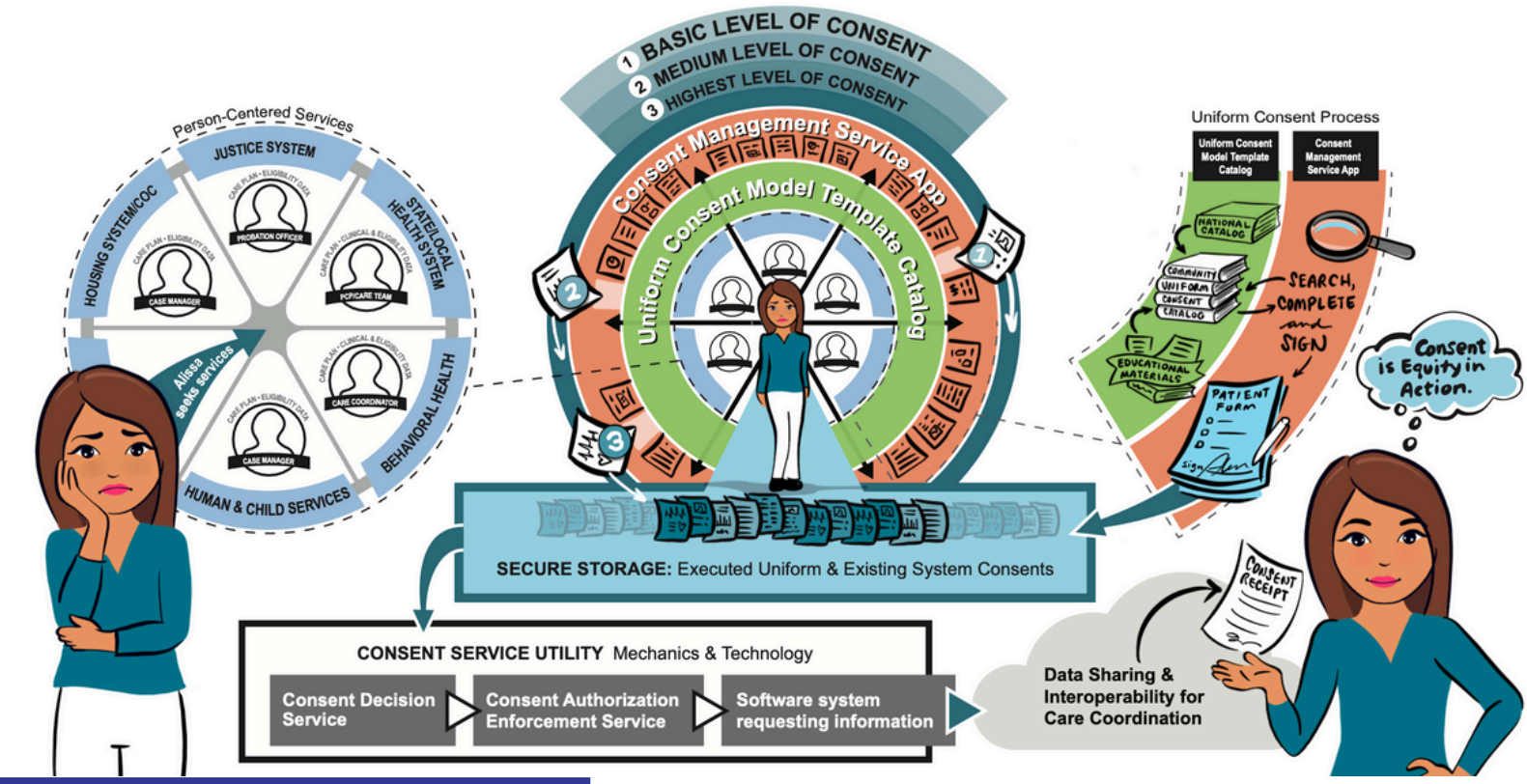
Consent Service Utility for Data Sharing and Care Coordination



The graphic illustration above summarizes a conceptual model and the technical processes necessary for obtaining and managing an individual's consent to share their personal data in ethical, secure and legal ways. The model, which this paper describes in detail, offers health, human services, justice, education and other human-serving organizations a customizable and replicable approach for automating consent, which is critical for improving care coordination and improving health and well-being outcomes.

Overview, Purpose and Recommendations

Over the last few decades, a consensus has developed among medical and human services providers, researchers and professional organizations that whole-person care is the gold standard for broadly improving everyone's health and well-being, while also helping to reduce racial and socioeconomic disparities and contributing to greater health equity.

Significant advances are being made toward achieving that aspirational goal as a growing number of government- and industry-supported initiatives chip away at longtime obstacles involving technology, governance and culture. Progress has been far slower, however, on a complex challenge that must be successfully addressed in order to build a smooth path – actually, more like a superhighway – toward achieving whole-person care.

The primary purpose of this White Paper is to offer a realistic, achievable roadmap for effectively surmounting that challenge, i.e., how to routinely, efficiently and ethically obtain informed, voluntary consent from patients/clients to share their personal, identifiable, sensitive information across the wide spectrum of service providers whose participation is necessary to deliver genuinely coordinated, individually-centered, whole-person care.

Our recommendations for accelerating progress toward that goal stem from four years of focused work on consent-related issues by Stewards of Change Institute (SOCI), its National Interoperability Collaborative (NIC) and hundreds of supporters and partner organizations, subject-matter and legal experts, researchers, industry and governmental officials, technologists, and other relevant professionals across the country. (History and overview of prior consent-related work is in Appendix A.)

In addition to numerous other activities, SOCI held Consent Learning Labs (CLLs) with the Healthcare Information Management and Systems Society (HIMSS) at its last two annual global conferences. Scores of thought leaders participated in these CLLs, with the explicit aim of synthesizing the extensive knowledge we've acquired and formulating specific, realistic next steps to build consensus and accelerate meaningful progress.

Our primary goal at the most-recent CLL, in March 2024, was to leverage the extensive talent, experience and insights of the 60 assembled experts to advance the design, functional requirements and architectural blueprint for a comprehensive Consent-to-Share Service Utility (CSU) conceptual model – which is the key to systematically addressing the myriad challenges to efficiently, effectively, ethically and securely share people's sensitive information. (Overview of 2024 CLL is in Appendix B.)

This White Paper summarizes Version 1.0

of the CSU model. It includes two key actionable recommendations that emerged from the 2024 Consent Learning Lab and prior consent work:

- Develop and test a prototype community-specific Consent Catalog of configurable, consumer-tested and executable consent forms, along with model language and boilerplate templates organized into modular sections that can be configured to accommodate an individual jurisdiction's laws, policies and requirements, for example, the Chicago Community Information Exchange (CIE). See next steps, at end of the report.

- Design a comprehensive roadmap for a CSU that would include a series of services: a national catalog of configurable model consent forms; consent services that interpret and act on executed consent forms; and guidance about the intersection of consent-specific technologies and standards to enable data sharing among the current technology ecosystems in specific jurisdictions.

Finally, by offering these recommendations and synthesizing years of insights and lessons learned, this White Paper aims to advise the range of organizations that are in the vanguard of implementing consent approaches, stimulate the design of proof-of-concept demonstrations, guide practice decisions and inform future policy, and improve information sharing across the Health and Human Services ecosystem, broadly including medicine, social services, education, nutrition, housing, justice, child and adult services, disabilities, and other relevant programs. (Note: "Health and Human Services" is used throughout the paper to refer to the broad array of programs and services encompassed by that term.)

Background and Context

Sharing personally identifiable, sensitive information across a range of service providers is a prerequisite to providing efficient, coordinated whole-person care to individuals and families with multiple needs spanning Health and Human Services. Over the past four years, through NIC and other initiatives, SOCI has led a large, diverse group of experts to develop a deep understanding of the complex legal, technological, organizational, procedural and system-oriented challenges for managing "consent-to-share."

Currently, many people must deal with disconnected systems and repetitive processes for providing both routine and sensitive information, potentially retraumatizing patients/clients as they seek to obtain the help that they and their loved ones require.

NIC's participants hail from all levels of government, industry, national associations, community-based organizations, the legal and technology communities, and philanthropy across the nation, representing physical and behavioral health, human services, education, justice and other "social determinants" domains. We share a common, core belief that when patients/clients start seeking services, consent-to-share should be addressed during the first encounter in a systemic, comprehensive and purposeful way.

Defining Consent-to-Share

Individuals have the right to informed consent, a concept grounded in the principle of autonomy that is foundational to American biomedicine and other fields, to understand the services offered to them, decide which treatments or services they receive, and know how entities may use their information. Unlike other types of consent, which may refer to express permission from a patient to receive a treatment or service or to participate in a research study, consent-to-share provides permission for health and social services organizations to exchange patient information with each other. Ideally, consent-to-share should be dynamic, meaning individuals can provide or revoke consent at any time, and granular, meaning individuals can indicate preferences for which data are accessible to providers at specific points in time.

The objective is to create standardized and replicable processes that enable individuals to choose what information they want to share and with whom, and then support the implementation of high-fidelity information exchange reflecting those personal preferences. Establishing a system to obtain and manage consent will reduce inter-organizational "friction," which will meaningfully improve data sharing, interoperability, operational effectiveness and efficiency. Most importantly, it will contribute significantly to better and more-equitable outcomes.

The CSU model described in this White Paper is a blueprint for designing, building, testing and operating a collaborative, permission-based system of sharing personally identifiable information in accordance with law, ethics and the personal preferences of those who might benefit from their information being shared for specific, intended purposes. It articulates the multiple processes and services needed for obtaining informed-consent decisions, managing those decisions, and protecting and sharing the desired information among providers caring for

people who need help from multiple systems. Currently, such individuals must deal with disconnected systems and repetitive processes for providing both routine and sensitive information, potentially retraumatizing patients/clients as they seek to obtain the help that they and their loved ones require. The story about Alissa Thomson (see call out box below) articulates her journey and is intended to highlight the complex processes she needs to navigate in order to receive coordinated care. It is part of the family of graphically illustrated and detailed user stories that SOCI has developed over the years.

Shelter-Based Care User Case
(Extension of the Thomson Family Scenario)

The following story is one of the initial use cases that the Chicago Community Information Exchange (CIE) plans to implement in 2025/2026. It is an example of how to extend the Thomson Family Scenario (see below) to incorporate other user stories while maintaining continuity and relationship among family members.

(Shelter-Based Care Narrative 2024 – Index Person: Alissa)

Alissa Thomson, 42, is the daughter of Randal and Geraldine Thomson and younger sister of John Thomson. She suffers from Bipolar Disorder, which has contributed to her life challenges. Manic episodes have resulted in overspending, high credit card debt and other financial crises that culminated in foreclosure of her home. Those financial stresses in turn triggered depressive episodes which left her emotionally paralyzed and housebound – missing work and losing jobs. In addition, Alissa found solace in food and drink, leading to weight gain and to early onset of Diabetes Mellitus Type 2.

With the loss of her employment and home, Alissa is struggling to rebuild her life. She relies on homeless shelters for housing, which also provide her with access to social and health services. As an insulin-dependent diabetic, she has some difficulties maintaining refrigeration of her insulin and being allowed access to the insulin and/or needles at the various shelters. She remains in contact with her sister. who provides some of her essential needs and a postal address to help with benefit maintenance.

Episodes of deep depression and very high blood sugar have resulted in visits to the Emergency Department and occasional admittance for hospital care. But those visits result in Alissa losing her place in a shelter, so she bounces from shelter to shelter around the city. As a consequence, she also ends up being bounced around the city's various hospitals, emergency care clinics and social services agencies. This results in some challenges ensuring that her healthcare and social care records are available to each new provider. Alissa is on the waitlist for her preferred shelter, close to her sister, but worries that each hospitalization could result in missing out on bed availability at that shelter.

Alissa's goal is to have stable housing, so she can effectively manage her health and housing needs. This requires an integrated approach, so she can get coordinated care across all agencies to prevent gaps during her social, behavioral and clinical health crises.

Overcoming Roadblocks, Reaping Benefits

The reality is that, until recently, insufficient resources have been invested in providing comprehensive, coordinated medical and human services. Therefore, there is no uniform and commonly accepted definition, view or model that includes all types of consents that may be needed across the broad spectrum of those services. Moreover, the staffs within most "people-serving agencies" operate with a limited perspective about the definition of consent and what type of consent is required to share information, usually driven by their programmatic or functional points of view or job requirements.

Another roadblock to comprehensive care is that there are no centralized repositories of executed consents, so obtaining coordinated services – or any services requiring information from a variety of different organizations – currently requires that a series of "one-off" consents be signed. Too often, these consent forms are difficult to obtain, challenging to understand and, once signed, often get lost in a physical or virtual filing system, causing a fragmented understanding of a person's consent history and approvals and resulting in the need to re-execute consent even when still current.

When dealing with multiple consent scenarios, understanding the uncertainty about the available and needed consents for sharing protected information may cause inconsistencies, unintended barriers to access services and unnecessary administrative complexity. Conversely, the benefits of having a comprehensive model would be far-reaching, from decreasing the burden on patients/clients to repeatedly supply the same information, to improving data integrity and enabling professionals to provide more-consistent and effective services that yield better outcomes. Moreover, rather than viewing consent as a burdensome process, we view the process of gathering and managing consent as a way to build trust and empower clients to make decisions about all their data. It is intended to build agency and transform the relationship with the provider. In other words, enabling ubiquitous consent-to-share service is "Equity in Action".

Evolution of the Consent-to-Share Utility Model

SOCI, with NIC's many participants, conceived the CSU concept at the inception of our work on consent four years ago. As a result of numerous online meetings, a conference and an array of other activities, we came to the conclusion that a CSU offers a path-breaking approach for managing many of the complexities that currently inhibit jurisdictions from equitable, ethical, legal, secure and efficient data sharing.

Like the case management and electronic health record systems with which it is designed to interoperate, the CSU would provide a suite of configurable tools and replicable services to manage consent-to-share. And, like some commercial electronic healthcare record companies, which

operate independently within defined systems, the CSU could be networked through current structures (Health Information Exchanges, Health Information Organizations and/or Community Information Exchanges, Health Data Utilities) to bridge different systems of record. The CSU would enable the authorized connection and accessibility to the content contained within Electronic Health Records (EHR), agency and Community-Based Organization (CBOs) systems.

Unsurprisingly, consent requirements, processes and solutions have been implemented by every program or domain according to their interpretations of applicable laws or jurisdictional policies and practices. As a result, there is no 360-degree understanding of a person's consent history or consent posture – and there is no realistic way of achieving such an understanding.

To streamline the processes of obtaining consent-to-share and implementing the resultant information sharing, it is important to level-set so that professionals across organizations and domains develop a common language and model of consent that complies with laws and codes and agreed-upon best practices when there is no legal guidance. In parallel, data and data-model standards must continue to evolve to reflect the critical components of consent, allowing widely implementable technological solutions to improve the efficiency and effectiveness of information sharing and curation of individual consents.

Developing the CSU Conceptual Model

The latest Consent Learning Lab (CLL) – held with support from InterSystems Corporation, HIMSS and the Robert Wood Johnson Foundation – was designed to focus explicitly on the challenges, merits and feasibility of developing a "Uniform Consent Model Template" (UCMT), which was identified at last year's CLL as a key gap in the overall CSU model.

The need for seamless information exchange across healthcare and human services organizations has become vital to effectively address the complex and interconnected needs of individuals and communities. This imperative is accompanied by a critical obligation to uphold the principles of privacy, autonomy and informed consent. As our understanding of the inextricable link between health and "social determinants" deepens, the development and implementation of universal consent models has emerged as a crucial step toward achieving a coordinated, person-centered approach to service delivery.

The key rationale for having well-established or "universal and uniform model" approaches to consent-to-share is to remove the burden of meeting legal, ethical and practical standards from each community implementing coordinated, multisector care. The diverse experts who participated in the CLL shed considerable light on the multifaceted challenges and opportunities associated with establishing consent frameworks. Their insights have

profound implications for institutions, policymakers, communities and, most importantly, the individuals they serve.

The 2024 CLL participants were asked to come prepared to share their knowledge, experience and relevant information, as well as to distill insights needed to complete the UCMT and overall CSU conceptual model. (CLL attendee list in Appendix C.)

The day's activities included:

- Learning from federal, state and county implementers who are actively planning, testing or deploying new consent models in their jurisdictions.
- Exploring the components and potential role of a UCMT for use by the CSU.
- Identifying functional and other requirements for consent services; e.g., consent template catalogs, consent management services and consent decision services.
- Building the body of knowledge and community of subject matter experts to help guide future learning, design, testing and development related to consent.

The cumulative efforts that informed the 2024 CLL have enabled SOCI to develop a conceptual model that can ultimately accommodate all the required and/or recommended consents needed to enable data sharing across the spectrum of human-serving domains. The conceptual model is flexible and can accommodate a range of consent frameworks, whether a UCMT has been adopted or if there are multiple consent forms in use across the domain.

This model is intended to provide guidance for organizations building replicable and customizable consent solutions. Such solutions will resolve some of the fragmentation and duplication that currently inhibit progress and make it challenging for individuals and families to obtain whole-person care, despite the best efforts of their service providers.

Too often, care coordination and other collaborative processes are halted or delayed due to the overwhelming burden of designing and implementing an agreed-upon consent model. To overcome that obstacle, the approach laid out here is extensible, customizable, modular and replicable. Utilizing this approach offers the advantage of streamlining processes to be better understood by and accessible to both individuals deciding whether to share their information and to professionals seeking consents.

This approach also addresses the composite view of the individual's consents or, in other words, their "Consent Posture." This is defined to include the number, type and complexity of a person's consents. Collectively, this can help inform the care coordinator and providers with a deeper and broader understand of the consent needs in relation to the services being sought/offered. By collating consents

across the domain to create the consent posture, the CSU will offer providers insight into the voices of their clients/patients – their wishes and desires relative to data privacy and service delivery – which will, in turn, empower and center the clients in the service delivery system.

The ultimate value proposition begins with improving clinical and social outcomes through faster, more-comprehensive and better-tailored service delivery. The CSU will streamline operational processes for obtaining, managing and revoking consent; understanding a person's overall consent posture; reducing complexity; and enhancing privacy, security and equity.

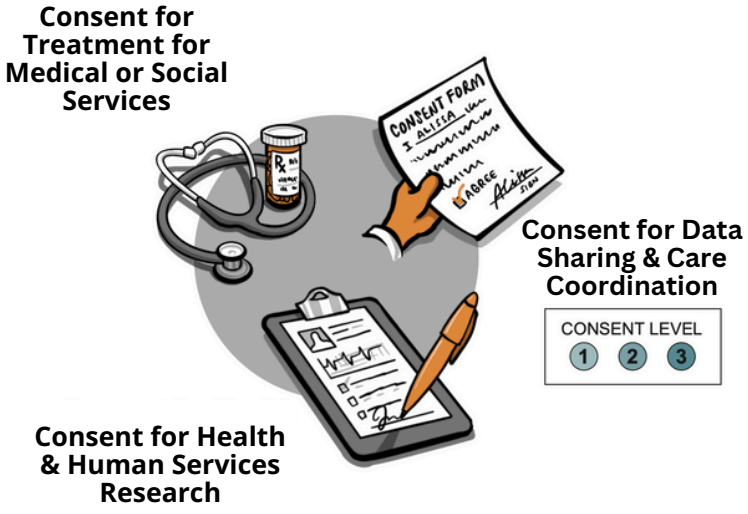
The following section provides a six-step process that describes the core concepts embedded in the roadmap for designing, testing, implementing and socializing the Consent-to-Share Service Utility Model v1.0.

Step 1: Recognize Consent is the Starting Point for Interoperability

There has been considerable confusion and misinterpretation about consent because professionals generally define it based on their own perspectives or for their own compartmentalized purposes. In practice, there are three types of consent: 1) to receive treatment for medical or social services, 2) to participate in health or human services research and 3) to share personal data for care coordination and other purposes

This White Paper, along with the proposed CSU model and other content for advancing integrated, whole-person care, focuses solely on the third definition, which includes the broad spectrum of health and human services programs.

Consent Types



- **Consent to receive medical or social services treatment.** In a medical context, this type of consent has been clearly articulated over time. For many social services programs, it is common/best practice - but not universal - to have clients provide some type of explicit consent to receive direct services.

    - Advance directives are a special example of when consumers document their wishes for future care, should they become incapacitated, both for consenting to and restricting actions on their behalf. Clinical trials in which a person receives different evaluations or treatment, depending on randomization or other research methods, is another special area requiring explicit consent.

- **Consent to participate in health or human services research.** Health services research, and its counterpart in other human-serving fields, also can require explicit consent from those whose trajectories and outcomes are being studied. Although this type of research often uses retrospective data that is de-identified and aggregated before analysis, identifiers may be needed to link data sets; in addition, certain uncommon characteristics may remain suggestive of identity, thus driving institutional review boards to require consent for a person/data to be included.

    - Consent is even more-clearly required for the use of individuals' protected health information (PHI) and their periodic survey data for prospective population-based longitudinal research.

- **Consent-to-share information for care coordination:** This encompasses a broad array of programs for which explicit consent may not be required by federal law. However, various human services programs may require different types of permission to share personal data based on state and/or local laws and regulations. These hurdles are erected to protect people from having their sensitive information exposed, deliberately or not, without their consent. There is a growing consensus that sharing any personal information should be a decision each person gets to make. This is "Equity in Action," and it is a human right.

Federal, state and local laws, policies and codes prescribe most consent requirements. Under the Treatment, Payment and Operations (TPO) Exception to the Healthcare Insurance Portability and Accountability Act (HIPAA) Privacy Rule – which applies to most US healthcare – it is expected that patients' PHI will be appropriately shared among treating providers, including referrals to social care agencies, unless it involves "specially protected" health information covered by other statutes.

Consent-To-Share Subtypes:

Under the umbrella term "consent to share," there are a variety of types of permission needed to allow information to flow in healthcare and human services settings:

- **Consent for disclosure or for exchanging data.** This allows healthcare or human services providers to share someone's personal or medical information with a third party, such as another healthcare professional or insurance company.

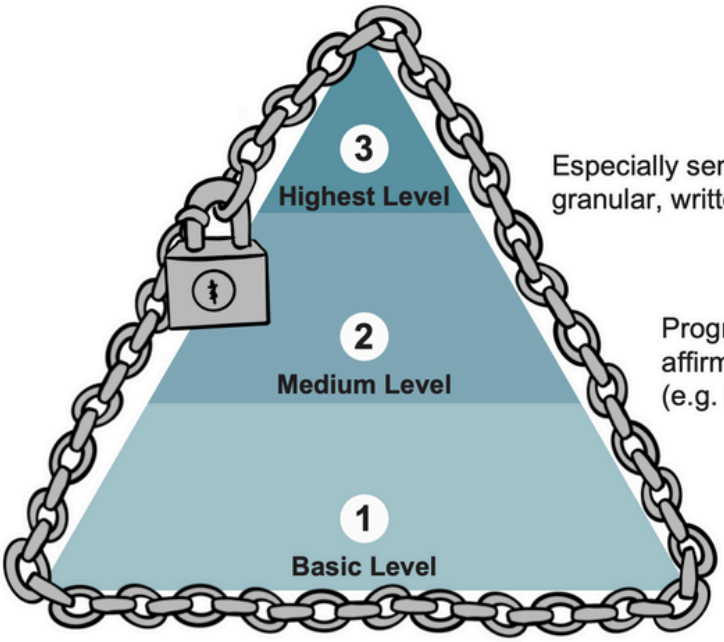
- **Consent for eligibility determination and enrollment.** This permits the disclosure of certain personal and financial information that is needed to determine eligibility for a public-assistance program; many agencies need the same information for consolidated applications.

- **Consent for referral.** This generally focuses narrowly on authorizing information sharing between referring and receiving agencies.

- **Consent for sharing administrative and demographic information.** This recognizes that people should have personal "agency" over all their data. While there are few laws requiring consent to share descriptive/administrative information, there is a growing consensus that computable consent solutions as envisioned by the CSU should include mechanisms to obtain and revoke consent for these data too.

For a considerable number of programs explicit consent to share information is not required by federal law. However, there is a growing consensus that everyone should be enabled to decide whether, when and with whom their personal information can be shared. This is "Equity in Action," and it is a human right.

Consent Types and Levels



Especially sensitive data requiring informed, granular, written consent to share with revocability

Programs or activities that qualify as sensitive and may need affirmative or implied consent for data sharing and other uses (e.g. HIPAA/TPO, referrals, eligibility, research, other)

Basic identity-related administrative data and potentially sensitive demographic data not necessarily requiring consent, but considered best practice for building trust

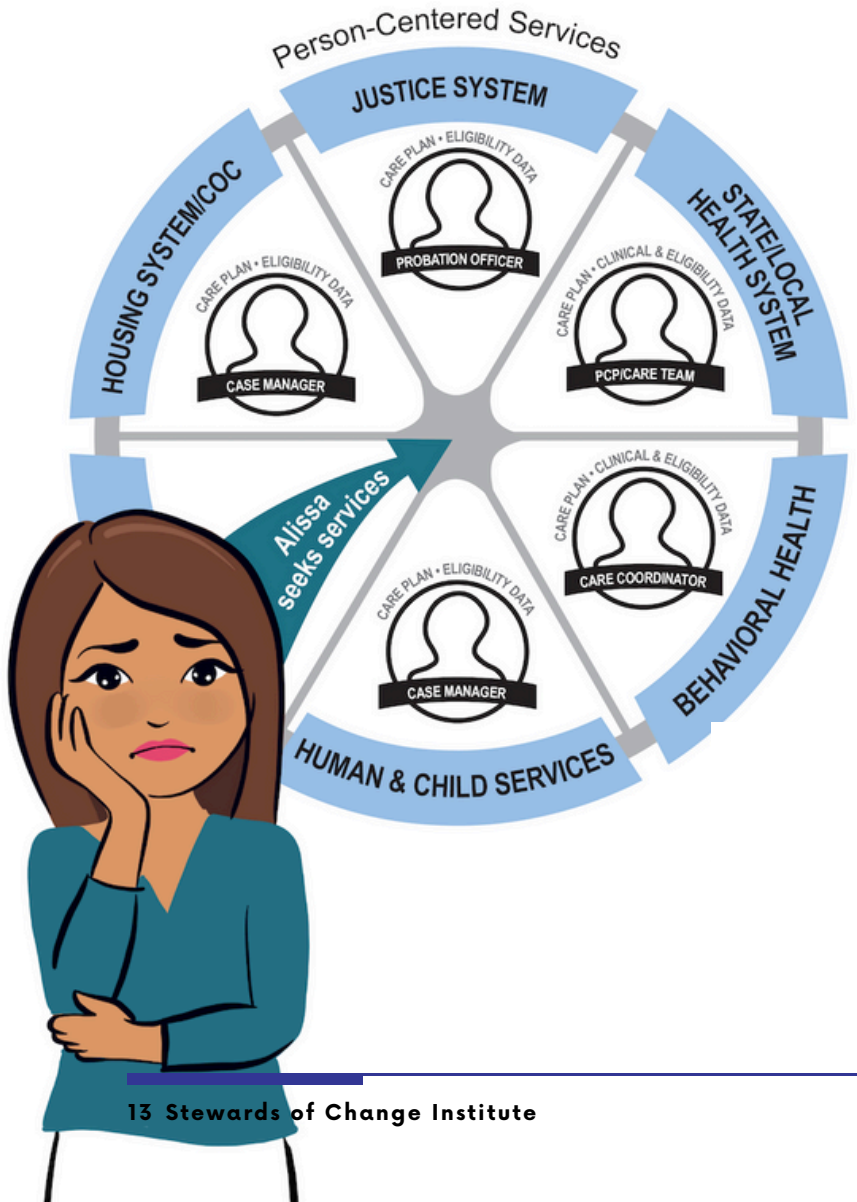
Pragmatically speaking, a well-functioning CSU could ease the reporting burden of patients/clients having to provide the same information over and over again. It may also provide security and comfort, given the risk of information breeches.

Important note: Although the CSU model is designed to facilitate consent-to-share, its catalog and registry functions could be equally useful for improving the management of the other two types of consent (treatment and research).

Pragmatically speaking, a well-functioning CSU may ease the reporting burden of people (patients/clients) having to provide the same information over and over again. It may also provide security and comfort, given the risk of information breeches.

Step 2: Embrace a Person-Centered, Equity-By-Design Approach

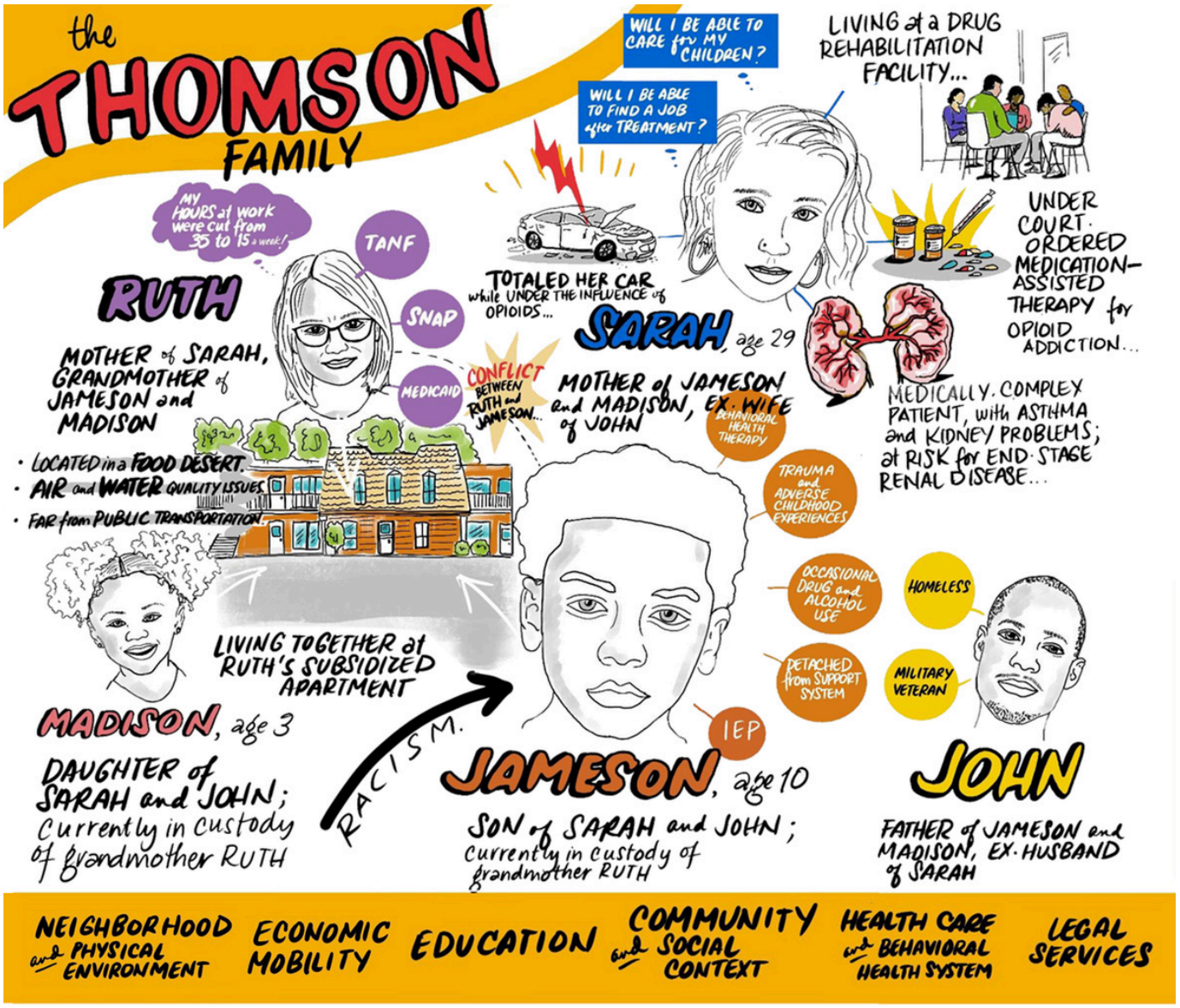
As indicated in the diagram below, the person, family and community should be situated at the center of the care ecosystem. This positioning highlights the need for effective care coordination across the spectrum of providers and organizations that exchange information to gain knowledge and provide services and support. The model depicts the range of domains and program types in which a patient/client might receive services – including social care, education, behavioral health, justice, housing and child welfare, among others – all with the ultimate purpose of enhancing outcomes through better data sharing. Achieving this goal will require organizations to invest in training workers, and leaders to think and operate in systematic ways, outside of narrow silos. SOCI has developed a training curriculum to facilitate this paradigm shift. (See InterOptimability Training Curriculum and Certification Program for details.)



Many program domains and systems requiring consent to share their information are represented here.

- Individual people and/or their families who are at the center of the Consent Service Utility model, must navigate multiple systems, programs and bureaucracies to access needed services.
- These largely siloed domains have few tools for obtaining and sharing information or resources, or for updating and/or revoking consent (internally or across domains, systems and programs)

Step 3: Acknowledge, Adapt and Coordinate with People's Families and Communities



Most people live in families and/or other social groups. To guide our thinking on consent, SOCI and its partners have developed, expanded and refined the Thomson Family scenario (illustrated above) for over four years to represent a complicated but realistic family situation involving a mother with complex issues, a divorced and separated father, a grandmother and two children. A narrative description of the Thomson Family scenario and personas is in Appendix D. It is written to reflect real-world, complex experiences facing families who need medical and social services.

Various elements of these fictional characters' lives are described in a variety

user stories that provide a granular view of their individual and intersecting needs. SOCI has cataloged and published these narratives in the Gravity Project Social Determinants of Health (SDOH) user story collection and on various proof-of-concept demonstration sites.

The Thomson family's stories can be employed to simulate how the CSU could assist with capturing and managing the variety of consent-to-share documents required by law and otherwise recommended to enable their challenges to be effectively addressed.

Having a common, shared set of scenarios and user stories can accelerate innovation and adoption of consent-to-share approaches by building a repository that can incorporate the myriad use cases that exist today.

To meet the needs of the Thomsons and millions of families like theirs, information must flow across multiple government agencies, private providers and community partners, among others. The processes for obtaining, storing and exchanging that information must be secure, reliable and explicit, because much of the content is private and sensitive (e.g., Sarah's opioid use disorder, son Jameson's adverse childhood experiences, grandmother Ruth's low-income status). Moreover, only those with a need to know should have access to it, and only if they have permission.

Having a common, shared set of scenarios and user stories can accelerate innovation and adoption of consent-to-share approaches by building a repository that can incorporate the myriad use cases that exist today.

Step 4: Use the Content Selection Tool to Match Programs and Consent Requirements

The diagram below illustrates a flexible tool and methodology for identifying and matching the specific programs and their respective consents that should be provided by the individual to meet the requirements and recommendations of the programs identified as a part of their care plan. The full array of available programs would be displayed initially. After the program identification and selection is completed for the individual, the tool will collapse to show only the specific programs identified for use by the patient/client, along with the various types of consents that are required and recommended. Think of it visually as a fan that spreads and contracts to reveal the specific programs and consents for each individual seeking or receiving services. (See appendix E for details about consent considerations and types; taxonomy details are in Appendix F.)

STEP 5: Design and Pilot the Consent Service Utility (Technical Overview)

Sharing personally identifiable, sensitive information across a spectrum of service providers is a prerequisite to providing efficient, coordinated "whole-person care" to those with multiple needs spanning health and human services. Effective consent-to-share processes should enable individuals to choose what information they want to share with whom, and then support the implementation of high-fidelity information exchange reflecting those personal privacy preferences.

Today, individuals face disconnected systems and repetitive processes for providing both mundane and sensitive, potentially re-traumatizing information to obtain the services they and their loved ones need.

The CSU model is a blueprint for designing, building, testing and operating a collaborative system of sharing identified personal information in accordance with law, ethics and the personal preferences of people who might benefit from their information being shared. It articulates the multiple processes and services needed for obtaining consent decisions, managing those decisions, and protecting and sharing the desired information among providers caring for multi-system-involved people. Solving consent is a huge, complex and highly technical endeavor that will take time, concerted investment and collaboration to achieve meaningful progress. Hopefully, learning from past efforts to implement Electronic Health Records should ideally expedite and streamline the consent-to-share journey.

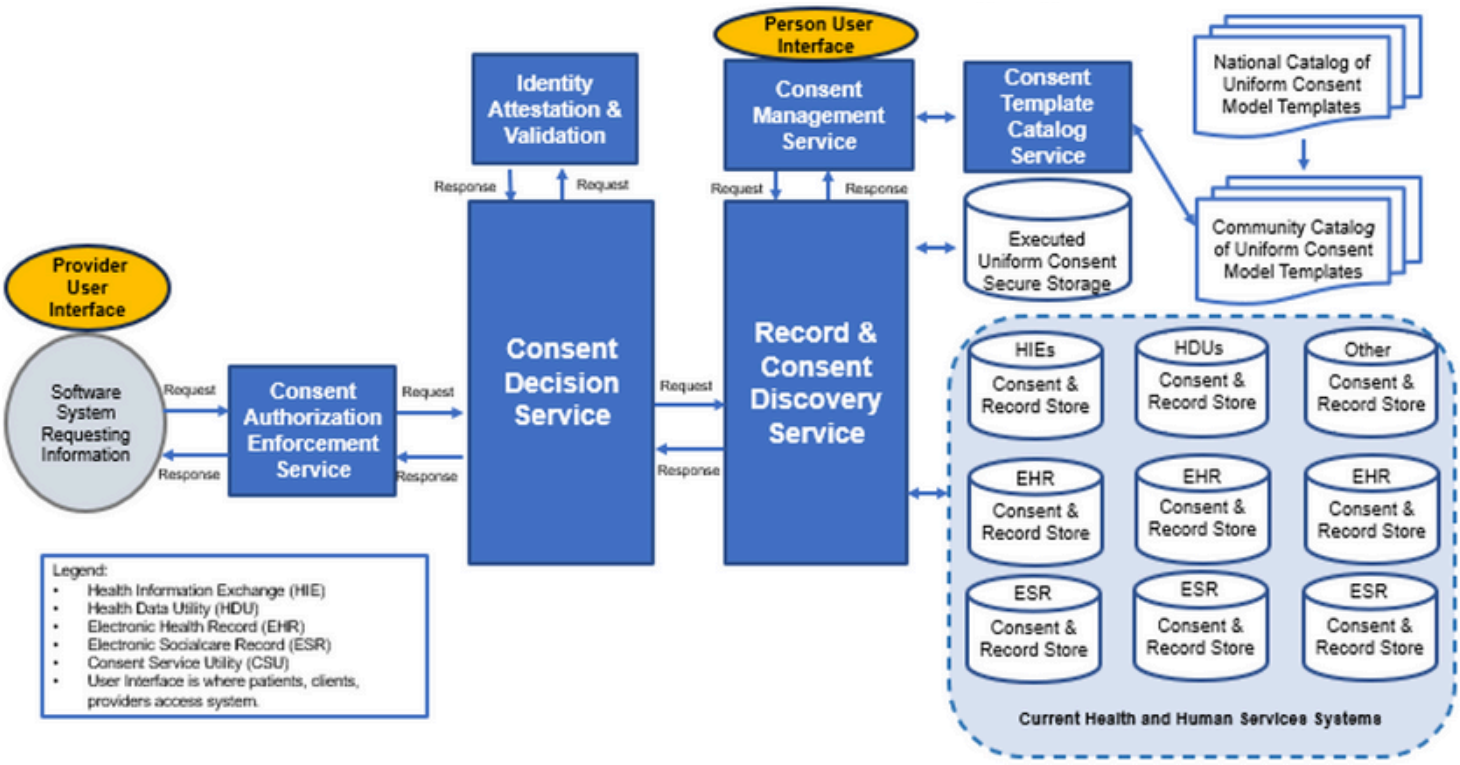
The following section provides a high-level overview of the technical and architectural requirements for the CSU. It includes the Uniform Consent Model Templates, Consent Template Catalog, Consent Management and Discovery, Consent Decision Services, and the current and emerging standards and solutions available to meet those requirements.

Individuals face disconnected systems and repetitive processes of providing both mundane and sensitive, potentially retraumatizing information to obtain the services they and their loved ones need.

Over the past decade, a significant amount of work has been done on security, privacy and consent standards by participants in Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), the Shift Taskforce, HIMSS, SOCI's Project Unify, the Gravity Project and other efforts that have

been integrated into this CSU model. In addition, there are now multiple open-source consent service implementations funded by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of the National Coordinator (ONC) through its Leading-Edge Acceleration Project (LEAP) grants, which in turn have become the basis for proprietary vendor commercial-off-the-shelf (COTS) products.

Consent-toShare Service Utility Model (CSU)



Uniform Consent Model Templates

An initial step in developing the CSU is creating Uniform Consents for the particular programs within a jurisdiction and/or provider organization. These consents can be sourced and customized from the National Consent Catalog (described below) and/or repurposed from previously developed ones found within the community's own store of consents. (For purposes of this paper, the term "community" is defined as comprising the full spectrum of health and human services providers within a designated geographic jurisdiction e.g., city, county, state).

A major challenge for consent-mediated information access is having access to consent forms that meet the needs of various community jurisdictions. Ideally, the community uniform consent forms are clearly written in easy-to-understand, non-coercive, plain language. The explanations about what people are

consenting to should be equally clear, verbally and in writing, non-coercive and approved by organizations that rely on using them.

One of the seminal ideas created during the 2024 CLL at HIMSS is the concept of "uniform consent templates," with model boilerplate language to ensure that the consent form contents are compliant with the law and have been vetted to ensure they are non-coercive and understandable by patients/clients for whom they are intended.

Multiple template examples may be needed for the same type of information exchange, such as disclosure of HIV/AIDS status to allow access to housing. In some states, the law requires a client's consent for a medical social worker to disclose this information to a housing agency, whereas in other states or jurisdictions, consent may be required by policy but not by law.

Additional modular templates could offer sections that could be repurposed for special, legally protected information, as well as boilerplate for consent execution, modification and revocation. These boilerplate modules could be mixed, matched and tailored for specific programs, and users could then publish their versions as finalized documents in subsequent iterations of the catalog for use by others across the community of care within the geographic boundaries.

CLL participants also recognized the value of both broad information-sharing consent forms – for example, the ones modeled in this year's Authorization to Share Confidential Medi-Cal Information (ASCMI) pilot in California – and ones that are very specific about what data could be shared and with whom whom – as modeled by the Arlington County Authorization The former may work well within a closed network of trusted partners with aligned goals and very similar training regarding information management. The latter may be necessary when it is important to restrict the information to what is often known in medical care as "minimum necessary," and to be explicit about what categories of providers/staff should have access to the information. Again, the catalog will offer high-quality versions of each template type. (Example consent forms are in Appendix G.)

The Uniform Consent Model Template Catalog

The other core idea created during the 2024 CLL is the concept of a Uniform Consent Model Templates Catalog. This catalog concept manifests in two ways:

1. A **national catalog** that would store consent form modules and examples of complete consent form templates for use by any community.
2. **Community-specific catalogs,** pre-populated from the national catalog with example consent form modules and templates, but also containing locally published, community-specific consent forms for download and use by practitioners and individuals.

The consent form templates stored in the national catalog would be reviewed and compliant with federal law, policy and practice. Model language would be used to identify the type of information to be shared, intended information recipients, and circumstances or restrictions on the authorized sharing. The resulting consent form modules and templates would be downloadable so they could be customized by individual communities' jurisdictions/ programs and subsequently configured to meet local law, policies and practices.

It is important to emphasize that the national catalog and all community-specific catalogs would contain publicly accessible form templates and would not be used to store an individual's completed and signed consent forms.

Having a catalog with a variety of options/templates for uniform community consent forms will allow the governance bodies managing care coordination projects to select whichever is most appropriate, while adhering to general standards (including, at a minimum, federal and state law, consumer-tested user interface design and appropriate language) that will be recognized by other agencies and providers outside the governance process. This approach will take a tremendous burden off agencies and their lawyers, who will no longer have to develop consent forms and test them with both agency staff and potential signers.

In addition to the forms themselves, educational materials can be part of the catalog. CLL participants were very clear that consent decisions should be supported, when possible, by human instruction and counseling. And when that is not possible, well-written and easily understood explanatory materials should be provided in a variety of languages and accessible to everyone, including people with lower levels of literacy.

There are two use cases for a Community Uniform Consent Catalog:

1.Collaborative organizations (e.g., Accountable Care Organizations, Community Information Exchanges or community schools' governance bodies) that can electronically access consent modules, templates and examples in the Catalog, and then work together to define one or more community consent forms and post the finalized forms to the Catalog.

2.Agency staff and people seeking services search the Catalog for their appropriate community consent form(s) and supporting educational materials. Ideally, this is an electronic process comparable to many transactions today, such as electronically signing mortgage papers. Alternatively, they download and print the standardized forms to complete on paper. The paper forms are designed to be digitized, so they become computable when they are uploaded as executed documents.

Once community uniform consent forms have been created in the **Community Consent Catalog**, a practitioner or an individual would use the **Consent Management Service and App** to search the Consent Catalog, select the appropriate consent form(s) for their community or organization, fill out the form and electronically sign it. Once an individual has started filling out a consent form, the form must be considered to contain potentially sensitive information, which would require any saved version of it to be stored in a secure CSU **Executed Uniform Consent Store**. Once an individual has executed (completed and signed) their Uniform Consent it is stored in the CSU **Executed Uniform Consent Secure Storage** as a Fast Healthcare Interoperability Resource (FHIR) for Consent.

The Uniform Consent concept allows an individual to fill out just one form for multiple community organizations, including different kinds of information. However, it might not be appropriate for every community organization to see all the contents of an individual Uniform Consent.

For example, depending on the design of the Uniform Consent form, if the individual asserts in the form that their substance use disorder information can only be shared with their therapist, it wouldn't be appropriate (or legal) to share that fact with the community food pantry that participates in the same uniform community consent form.

Gathering Consent

Technologic approaches can also be used to streamline consent processes. Currently, consent can be captured using different media, as described below. As it becomes increasingly acceptable to the population being served, and as more agencies modernize their systems, consent capture and management will become increasingly digitized.

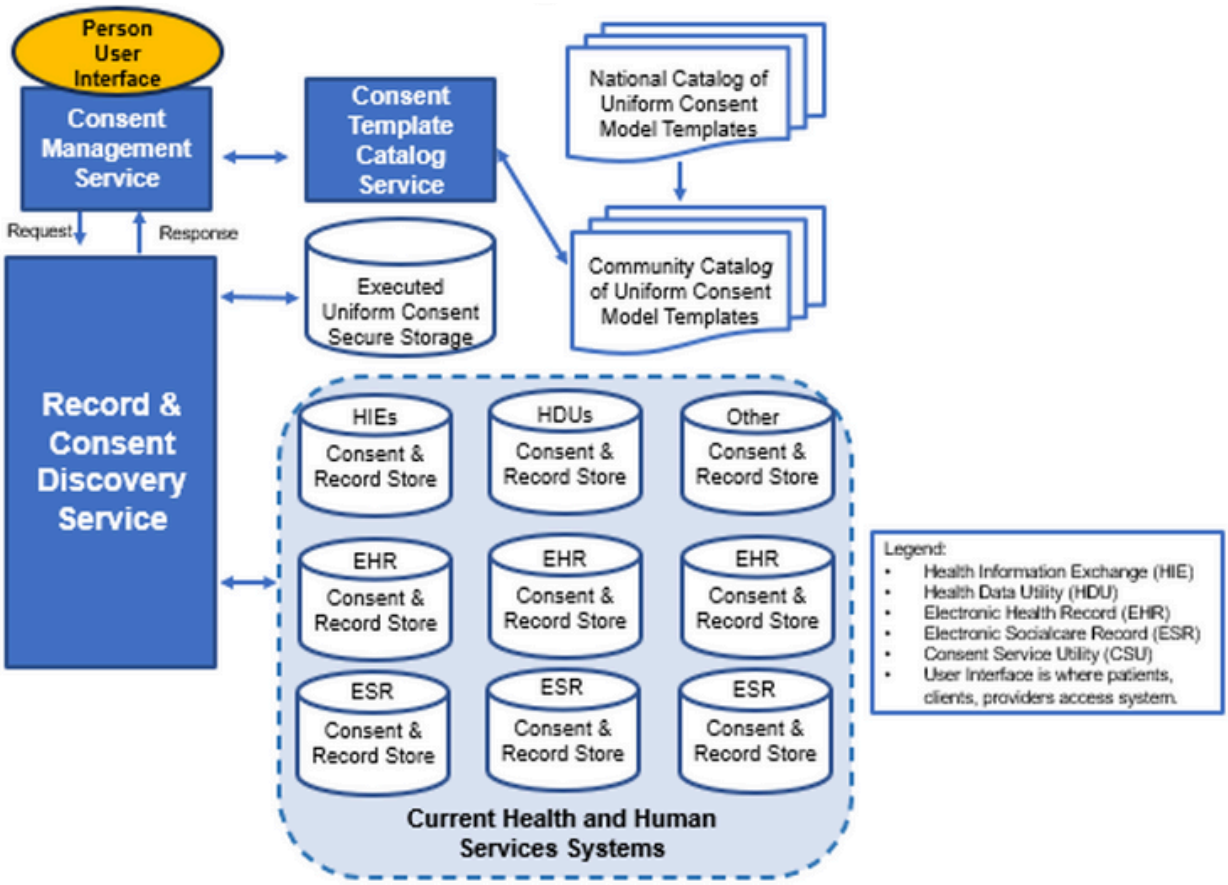
- Paper Consents. Traditionally, patients/clients have filled out and signed paper forms, which are filed and rarely seen again - or used. In today's highly distributed internet environment, this process is problematic since neither computer systems nor remote staff look for paperwork in physical filing cabinets.

- Digital Indication of Paper Consent. Electronic records systems enable the ability to at least digitally indicate a paper consent has been provided and/or updated. This indication is not complete enough, however, to indicate exceptions to the consent or any specific categories of information.

So, once an individual has executed their Uniform Consent form and it is stored securely in the CSU Uniform Consent Storage, the Consent Management Service would parse the form to extract only information that is appropriate for each of the community organizations with their own internal consent stores and distribute

the new (or updated) FHIR consent to those organizations. (One way to accomplish this is to request the consent form FHIR resource from the Consent Enforcement Service on behalf of each organization, which would redact any information the consent itself asserts they should not be able to see.)

Consent Management Workflow



The **Consent Management Service** can be used by the individual or practitioner to find the executed or in-progress Uniform Consents in the secure storage. They can also find out what other systems have executed consents, either redacted versions of the Uniform Consent or legacy consents. These consents can then be managed – updated or revoked - by the individual or authorized practitioner.

There are three ways current electronic records systems can make use of consents created by the Consent Management Service from the Consent Catalog:

1. If a system has its own consent store, which includes consents that were redistributed to it via the Consent Management Service, it can use those consents internally to make decisions regarding information sharing.

2. If the system does not have its own internal consent store or is making a request of another system with unknown consent support, the system, HIE or Health Data Utility (HDU) can make the request for information through the Consent Service Utility Proxy. The CSU Proxy Service will fetch the requested information from one or more systems of record, along with the associated consents, calculate what redactions are needed for the returned records and deliver redacted information to the requesting system.

3. In the future, if the CSU and the source system supports it, the CSU can calculate an authorization token, such as an OAuth 2.0 token for use in making an independent request for information. This is not currently supported in LEAP-CDS or Consent2Share open-source systems.

The Consent Service Utility

When an electronic records system initiates the process to access information on behalf of a practitioner or organization from any of the other electronic systems in the community, it requests or searches for that information through a Consent **Authorization Enforcement Service** API (which may be a FHIR API). This service uses the **Discovery Service** to find records that match the request and uses the **Consent Decision Service** to calculate consent to share the discovered records.

Data Segmentation for Privacy

The ability to attach data privacy markings to specific subsets of information is also particularly helpful for documents that may contain mixed information, such as within a medical primary care progress note that discusses both physical and mental health issues. The same may be true of an intake evaluation at a human services organization, such as a Family Success Center or Area Agency on Aging, to broadly assess an individuals's or family's circumstances and needs.

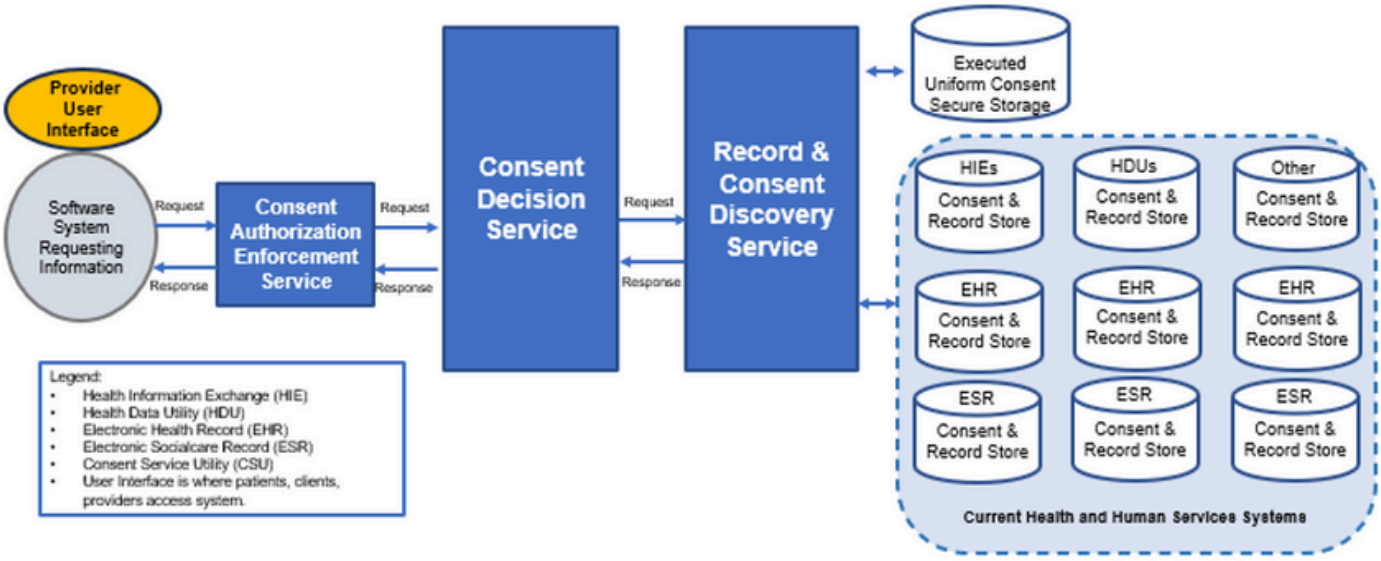
The Consent Decision Service "reads" the returned consent document(s) associated with the records returned from one or more source electronic records systems (e.g. EHRs, Case Management Systems, etc.), reviews the returned records for any internal "Data Segmentation for Privacy" markings, and any jurisdictional or organization policies to calculate merged "consent-to-share" for the requested records. This calculated consent is then used to create requirements for removal of any information in the records that the requester is not allowed to see.

Finally, the requested records and the requirements to remove information from the records for a specific requestor (a.k.a. "consent obligations") are returned to the Consent

Enforcement Service, which then uses the consent obligations to redact information from the records before returning those records to the requestor through the API.

In summary, all the components outlined in the previous sections and illustrated in the graphic below can be thought of as "middleware" of the CSU. As implemented together, each instance of the utility fulfills the business requirement for consent-to-share, based on the jurisdiction's actual laws, current systems and governance.

Consent-to-Share Service Utility Model (CSU)



Step 6: Assess Organizational Readiness and Develop Change-Management Plans

Implementation of a CSU, like all large-scale organizational change initiatives, requires significant attention and investment for planning, training and managing operational and systems-level change. During the 2023 CLL at HIMSS, we delved deeply into the major operational domains that need to be addressed to improve the coordination of services cutting across siloed hierarchies and bureaucracies.

We identified five areas that require significant attention, organizational analysis and process improvement/training by leadership to implement a "systems of systems" approach. (See SOCI's final report from 2023 CLL for further details.)

1.Governance and Organizational Development

The goal in this area was to create an integrative framework that ensures effective communication, delineates decision-making authority, and promotes harmonious cooperation among participating organizations and agencies. One way to achieve that goal is to weave these diverse entities into a comprehensive network that can recognize the synergies among providers and then meet the needs of the populations they serve.

2.Equity

This area is rooted in the understanding that people with varying backgrounds and life experiences have unique perspectives and needs when seeking or receiving care, especially if they are involved with multiple systems. The goal is to surmount systemic challenges such as socioeconomic disparities, racism, homophobia, and other problems that can inhibit equitable access to services and supports. Those also include hurdles relating to stigma, misuse of personal information, and inequitable access to technology, among others.

3.Law, Privacy, and Confidentiality

This key area covers the statutes governing the balancing act between individual privacy rights and the need for personal health information disclosure. It encourages a shift away from a risk-averse “culture of no” and calls for clearer and more synchronistic health data privacy laws. Additionally, it endorses the adoption of consent standards for the sharing of health-related information that are voluntary, informed, understandable, and meet competency requirements.

4.Technology and Information Management

This key area emphasizes the need for the secure, responsible and accurate exchange of data within and across care domains, enabled through interoperability standards. It recognizes the unique needs of data sharing in social care compared to health care and highlights the importance of consent in the sharing of sensitive information. It also emphasizes the need for tools, models, and competencies that can facilitate effective collaboration across silos.

5.Interagency Systems and Administration

This area highlights the necessity for a systems approach to achieve whole-person care. Such an approach necessitates a shift in perspective and dialogue in order to instigate changes within and across systems and organizations to facilitate the necessary transformation. It also acknowledges the key role of technology as an enabler in the process.

These five areas can serve as the foundation for organizational readiness to implement a Consent Service Utility. Having a clear understanding of organizational competence in each area is critical for identifying strengths and areas of development. As part of any change effort, the organization should conduct a thorough assessment to guide leadership's attention and investments on the appropriate timeline and road forward.

Maturity Matrix

The following maturity matrix example provides a model to assess organizational capabilities and competency in five areas using standardized, rubric-based criteria. After completing the maturity matrix assessment, the results can be plotted on a roadmap to guide organizational change management programs and implementation timing.

	Organizational Change Readiness Maturity Matrix Rubric Levels (Low to High)				
Activities:	*Lvl 1*	*Lvl 2*	*Lvl 3*	*Lvl 4*	*Lvl 5*
Governance and Organizational Development					
Equity					
Law, Privacy and Confidentiality					
Technology and Information Management					
Interagency Systems and Administration					

	Timeline For Implementing Organizational Change Initiatives				
Activities:	*Qtr 1*	*Qtr 2*	*Qtr 3*	*Qtr 4*	*Qtr 5*
Governance and Organizational Development					
Equity					
Law, Privacy and Confidentiality					
Technology and Information Management					
Interagency Systems and Administration					

Recommendations and Next Steps

The actionable recommendations that emerged from the 2024 CLL, which SOCI and its partners intend to implement, include:

- Design a CSU model that includes a community-specific catalog of configurable Consent Forms; Consent Decision Services that interpret and act on executed consent forms; and guidance about the intersection of consent-specific technologies and standards with current technology systems and infrastructures.

    - SOCI is working with Data Across Sectors for Health (DASH) and the Illinois Public Health Institute (IPHI) to develop a tailored instance of the CSU for the new Chicago/Cook County CIE. Specifically, with our partners, we will:
        - Design a technical approach and process for defining model consent forms based on data standards to enable uniformity, automation, management and use by consent-support services
        - Design an approach and process that is ethical and legally compliant for ensuring that cataloged consent templates meet standards for being accessible to those who will customize them for their jurisdiction and/or program.

    - SOCI plans to present a working session in partnership with Civitas Networks for Health at their annual conference (fall 2024) to present the comprehensive CSU model and to advance the work plan for the coming two years.

- Create a virtual “living” National Consent Catalog with model consents that would be regularly updated and expanded. It would contain configurable, consumer-tested and executable consent forms that meet federal minimum legal standards, along with boilerplate templates and model language organized into modular sections. The Catalog would be accessible to individual jurisdictions and programs as the standardized source for consents that could be adapted and configured to meet state and/or local laws, policies and practices.

    - SOCI will work with DASH and other implementation partners to design and develop an initial prototype of the virtual Community-Specific Consent Template Catalog for the Chicago CIE project over the next two years.

Next Steps for the Consent-to-Share Community

- Strengthen and build a National Consent-to-Share Workgroup to plan and advance research, idea exchange, convenings and best practices.

- Identify, learn from and convene jurisdictions that are already designing and/or testing innovative consent models.

- Advocate for funding to drive infrastructure development, including information technology standards development and deployment; model legislation; executive-level policymaking; governance models; and ongoing legal consultation.

- Research emerging trends, opportunities or new directions that may have future impact, such as generative AI and natural language processing.

Conclusion

Consent-to-Share is a critical component for realizing the potential of a more-equitable, culturally competent, effective and efficient system of care that embraces and enables value-based, whole-person, coordinated care initiatives across the service spectrum. It is critical to accommodate the unique data-sharing and legal requirements of each program, agency and/or organization. As described in prior documents, and further detailed in the appendices to this report, overall success depends on addressing multiple, interwoven functional elements, including governance, law, equity, technology and systems.

By addressing the findings, recommendations and next steps discussed above, all stakeholders (healthcare, human services, education, justice and other relevant domains) can collaboratively advance the development, testing and adoption of a uniform consent model, enabling more-effective, secure and ethical information exchange, while respecting individual autonomy and privacy.

Appendices

A. History and Background
B. Key Findings from the 2024 Consent Learning Lab Conference
C. Participant List from 2024 Consent Learning Lab at HIMSS
D. Thomson Family Scenario User Story Description
E. Consent Considerations, Types and Usage Guidance
F. Consent Taxonomy Matrix
G. Consent Template Examples

Appendix A:
History and Background: Evolution of SOCI's Consent-to-Share Initiative

Over four years ago, SOC Institute decided to focus sharply on accelerating progress on consent-to-share for a few reasons: Because it is a prerequisite to safe, secure and effective information sharing and interoperability between systems and programs. Because it is a key to improving health-related outcomes, reducing racial and socioeconomic disparities, and advancing health equity. And, since controlling one's own data is (or should be) a human right, making that process saner and more reliable is the ethical thing to do.

It is also eminently clear – from our research, convenings and other efforts – that driving progress on consent-to-share is a huge positive for the professionals who provide medical and social services. Indeed, efficiently addressing consent at the start of any interaction with their patients/clients will alleviate many of the organizational, legal, governance and technical challenges that "people-serving" organizations everywhere encounter.

The culmination of SOCI's work on this critical issue is a comprehensive conceptual model, described in the accompanying White Paper, which provides foundational guidance for agencies, organizations, governmental entities and others striving to achieve the same goals as we are. We hope an increasingly united Consent Community will adopt, refine and expand on this model, because progress is more rapid and comprehensive when it is fueled by collective learning and collaboration, rather than siloed individual efforts.

The following are summaries of SOCI's primary consent initiatives over the past four years. Fuller descriptions are available on our website.

National Action Agenda 2021

SOCI held an online national symposium, in partnership with the Stanford University Center for Population Health Sciences, in early 2021. It was the culmination of a year-long, highly collaborative effort titled the "National Action Agenda to Advance Upstream Social Determinants and Health Equity." Several recommendations grew out of that event and the work that preceded it; the primary one was to modernize the archaic processes by which individuals provide consent to share their personal data.

One key action item following the symposium was to conduct an environmental scan and report its findings. *Modernizing Consent to Advance Health and Equity* identified consent practices across the nation and examined the legal, technical, equity and governance

challenges inhibiting data sharing. The scan offered the first in-depth look at consent-related activities in a decade. Primary findings included:

- **Identity management is a prerequisite for implementing any automated consent-to-share practice/solution**. If an individual's correct identity cannot be determined with certainty, then core issues such as privacy, data-sharing and informed provider services cannot be adequately, ethically addressed.
- **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** regarding privacy and consent issues. They often do not align with each other or lack clarity about how they interact, thereby leaving gaps and causing confusion even on fundamental issues.
- **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, caregiver or 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.
- **Outside of Health Information Exchanges and Community Information Exchanges, 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 impedes granular data sharing**. Nevertheless, existing open-source technology could serve as the foundation for a Consent Service Utility.
- **Financial investments and education are necessary** to advance and sustain learning regarding the laws, regulations, policies, data and technologies that will have an impact on information consent.

Consent Learning Lab 2023

SOCI brought together 65 highly accomplished subject-matter experts – representing healthcare, social care, education, housing and other domains – for the first Consent Learning Lab with HIMSS in April 2023. The convening was designed specifically to

address consent-to-share's challenges because of the national implications for better integrating the social determinants of health, improving person-centered care and enhancing care coordination across sectors.

Importantly, this CLL highlighted five domains – Governance, Legal, Technology, Equity and Systems – that are essential for building, integrating and adapting organizational structures to something as complicated and important as consent.A detailed discussion of these five domains is found in SOCI's full report about the 2023 CLL.

Key Policy Recommendations

The Learning Lab's discussions were designed to identify actionable policies and practices that could be applied in the near term (2023-2024) to advance consent, while protecting individual rights, promoting equity and fostering ethical decision-making. Toward that end, participants made a series of high-level, longer-term, strategic recommendations, all of which are described in the full CLL report.

What became clear from our discussions is that more progress clear can be made, but it will require federal and state leadership, support, commitment and resources. Against that backdrop, two significant, immediate-term recommendations are highlighted below:

- Strongly encourage states to prepare/submit an Advance Planning Document (APD) to the Centers for Medicare & Medicaid Services (CMS) specifically requesting 90/10 Federal Financial Participation (FFP) to design, test, and implement consent-to-share initiatives. CMS has stated publicly and privately that 90/10 FFP is warranted when the investment will "benefit the Medicaid Program."
  That clearly would be the outcome of improving a state's technical ability to share myriad health and social care data more effectively, securely and ethically. States can also submit an APD to fund Maintenance and Operations with 75/25 FFP. Starting an effort with such secure funding would clearly improve its prospects for success.
- Advocate and educate on the need to integrate consent-to-share practices for social care and other programs into key existing laws, regulations and policies that address medical/clinical issues. It is critical to seize the moment, while the overarching rules are being formulated and implemented into day-to-day practices and solutions.
  Examples include the 21st Century Cures Act, the Trusted Exchange Framework and Common Agreement (TEFCA), the Modernization Initiative of the Office of the National Coordinator for Health IT (ONC) and the Centers for Disease Control and Prevention (CDC), and Section 1115 Whole Person Care Waivers from CMS.

Consent to Share: California's Opportunity to Modernize Cross-Sector Data Sharing (2023)

This report examines the essential policy, legal and technical components that must be reconciled to scale consent-management services from promising county-level pilots to a statewide information exchange. The basis for this strategy is rooted in informed consent and its ability to facilitate appropriate data sharing, enabling the state to enhance service delivery and improve health outcomes. This report can be accessed at this link.

The recommendations in this paper are essential to realizing California's potential to attain efficient, ethical and holistic care for its residents. They include:

1. Devise and launch education and communications programs to accelerate the adoption of state legal interpretations regarding consent-to-share and ensure their alignment with sub-regulatory guidance.
2. Advance efforts to develop consent-to-share technology, technical standards and policy.
3. Prioritize the development of a standardized consent form that is informed by findings from the Authorization to Share Confidential Medical Information (ASCMI) pilot.
4. Establish statewide consent management programs in parallel with the execution of the Strategy for Digital Identities and in partnership with agencies beyond the California Health and Human Services Agency.

Appendix B:
Key Finds From The 2024 Consent Learning Lab Conference

The 2024 CLL was designed to build on SOCI's prior research, discovery, analyses and symposia that brought together national subject matter experts to identify next-generation processes for obtaining and managing consent-to-share protected information across the broad spectrum of relevant programs, agencies and sectors.

Our convening at the 2024 HIMSS conference focused specifically on the concept of a Uniform Consent Model Template. During the 2023 CLL, we explored a standardized model including five domains of focus (see 2023 CLL summary for details) that interface with relevant stakeholders to streamline service delivery and enhance the individual's experience. The vision is to provide a template that significantly reduces the burden of designing and implementing a consent process that can be readily replicated, configured to meet local needs, and integrate with legacy governmental and private systems.

From a workflow perspective, this means consents for information sharing and services would be accessible to both agency staff and the individuals who provide (or restrict) their approval. Both the consent language and processes would be vetted and honored by all parties. From a technology perspective, a "modular uniform consent template" could serve as key component of a Consent Catalog and a Consent-to-Share Utility. The modular sections, boilerplate templates and executable consent documents in the catalog would be discoverable. With appropriate authorizations, they also could be downloaded or electronically completed, altered, or voided.

Once a consent form was completed and executed, it would become protected information associated with the person who signed it, and would be retained in a Consent Store separate from the general consent form catalog. In advanced systems, the CSU and the generic consent form catalog would work in conjunction with the Consent Store as an electronic gateway between the systems of record for consents needed to share protected information.

It was evident from CLL conversations and report-outs that many participants – including federal, state and local governments, healthcare providers and other stakeholders – are prepared and eager to work toward advancing this model. Making changes to incorporate social drivers of health and well-being will depend on systematic and scalable methods that enable sharing protected information. While this vision remains a future state (likely 5 to 10 years), there are communities nationwide that are making encouraging progress innovating and strengthening consent-related policies, practices and programs.

A few states and localities, many of which have participated in the CLLs, have begun to test and implement innovative consent-management systems. These pilot systems give consumers greater control over the sharing of their information and provide regulatory compliance for protected information:

- California Department of Health Care Services
- Washington Health Care Authority
- Broward County, Florida Children's Services Council
- Arlington, Virginia County Department of Human Services

These examples range from situation-specific, as with Broward County's very-targeted approach to obtaining consent for involuntarily committed youth suffering mental illness, to CalAIM's near "universal consent" model. The latter would enable consumers to provide consent in a single place to facilitate seamless information exchange and care coordination across the full spectrum of health and social services tied to their Medicaid accounts.

Whatever their approach, there is also a growing recognition in each jurisdiction that obtaining consent should be an ongoing, person-centered process, and that it should encompass both public and private health insurers, providers and payers. By empowering individuals to manage their consent preferences, these community-driven initiatives are enhancing consumer privacy, trust and engagement with critical services.

Learning Lab Methodology and Findings:

It is crucial for health and human services organizations to properly obtain the appropriate types of informed consent to ensure ethical practice, respect for individual autonomy, and compliance with relevant laws and regulations. Because of the complexities involved, however, this too often does not happen.

Instead, because their information lives in silos, patients/clients are required to provide consent again and again, whether to obtain only healthcare or to access a broad array of services linked to common needs such as poverty, disability or trauma. This reality illuminates the need to adopt a system-of-systems engineering and training approach to address the innumerable permutations and variabilities of laws, regulations, policies and practices.

The 2024 CLL curated a series of sessions to formulate next steps to advance this important work. They included one expert panel of consent project implementers; another with senior ONC leaders and a representative from the Chesapeake Regional Information System for our Patients (CRISP); and two interactive sessions that delved into the range of consent types and requirements, and then focused on understanding select consent templates and how they applied to complex, realistic user stories drawn from real life.

These activities vividly illustrated the variability of consent and why a CSU is needed and should be prioritized. Furthermore, the CLL and its participants provided important knowledge and ideas for building the conceptual model and frameworks needed to guide future development and testing.

Panel 1: The Art of the Actual

In this session -- titled *Consent-to-Share Vision, Approaches and Models for Managing Multi-system Involved Clients* -- panelists presented their experiences designing, testing and/or implementing comprehensive, universal consent approaches and discussed lessons learned. These approaches were considered as potential models for designing replicable solutions to accommodate the broad range of consents required by individual programs and laws, especially for people involved with multiple programs.

Each presenter provided details on consent-to-share initiatives that are in development, designed to overcome current system inertia around information sharing – two generated out of behavioral health (WA and FL) and the third (CA) encompassing the broader Medicaid population to meet the diverse health-related social needs outlined by the CalAIM initiative.

Kristine McCoy MD, MPH, Family Physician, SOCI Senior Consultant moderated this discussion. The panelists were:

- Srisiti Sharma, MD, MPH, Informatics Medical Consultant, Enterprise Data and Information Management, California Department of Health Care Services
- Jerry Britcher, Assistant Director, Chief Information Office, Enterprise Technology Services, Washington State
- Sue Gallagher, Chief Innovation Officer, Children's Services Council of Broward County, Florida

Key Findings

Focused use cases have clear and broad potential for extensibility/reusability. Britcher and Gallagher described in-process consent-to-share efforts designed to fit specific needs – the sharing of specially protected behavioral health information in Washington State and care coordination for minors put on involuntary psychiatric holds in Broward County. The former was a healthcare-specific use case and the latter, triggered by a healthcare event, explicitly involves schools and potentially juvenile justice and child protective services for a very specific population.

Britcher made it clear that Washington's initial focus on substance use disorder treatment was foundational to plans for a care-management and coordination solution across multiple state agencies and a community information exchange. He called it a "coalition project" that would extend consent-to-share to corrections, agencies serving tribal and disabled populations, and providers of economic services such as vocational rehabilitation, SNAP, and TANF. While CalAIM is already broad, Sharma said there is also a need for an ASMCI-like consent process to enable successful reentry programs for those exiting incarceration.

Human mediated consent processes are critical. Broward County's consent-to-share process was designed in concert with a participatory action-research project involving young people subject to the state's Baker Act for involuntary 72-hour psychiatric evaluation. They provided critical insights into what types of coordination are required for successful outcomes, and they and their parents vetted the consent language to ensure it could be understood by youth and families like theirs.

In the three ASCMI pilots, MediCal beneficiaries said they were very likely to sign the form if it was presented by an informed, allied person like a community health worker. Pilot respondents also provided feedback on future improvements to the process, such as edits to the reading level of the consent language. In Washington, the focus to date has been on ensuring the medical provider community understands the consent purpose, language and process, so it will be appropriately implemented.

Accessibility and consistency of consent processes go hand in hand. Bricker described his state's intent to have consent processes easily accessible through cloud-based solutions that would ensure they can efficiently replace current uneven distributed processes. He also noted that data standards for both consent and commonly required data elements will help, but change management will be needed on many fronts to ensure those standards are broadly adopted.

Sharma reported that the ASCMI pilot highlighted the need for many modalities of consent processes (e.g., paper, tablets, mobile phones) to ensure they are available under a wide variety of circumstances to both service providers and people seeking services. She also encouraged leveraging existing interoperability and data-exchange capabilities to manage both consent and the resultant information sharing.

Creating a Consent Culture is Paramount. Gallagher spoke compellingly of the need for a "consent-first culture where we're really centering the human experience and agency around this." She noted it is critical to have resources to create the human infrastructure, legal language and technology to support fully informed and non-coerced consent.
All three panelists agreed human mediation of the process is vital, regardless of how good the technology or how clear the consent language. Gallagher highlighted that relationships among providers are essential because they are the basis of confidence in the consent process and encourage its robust use. In addition, they fuel collaborations to support patients/clients once information sharing is enabled.

Interactive Activity 1: Consent Bingo and Pyramid Segmentation

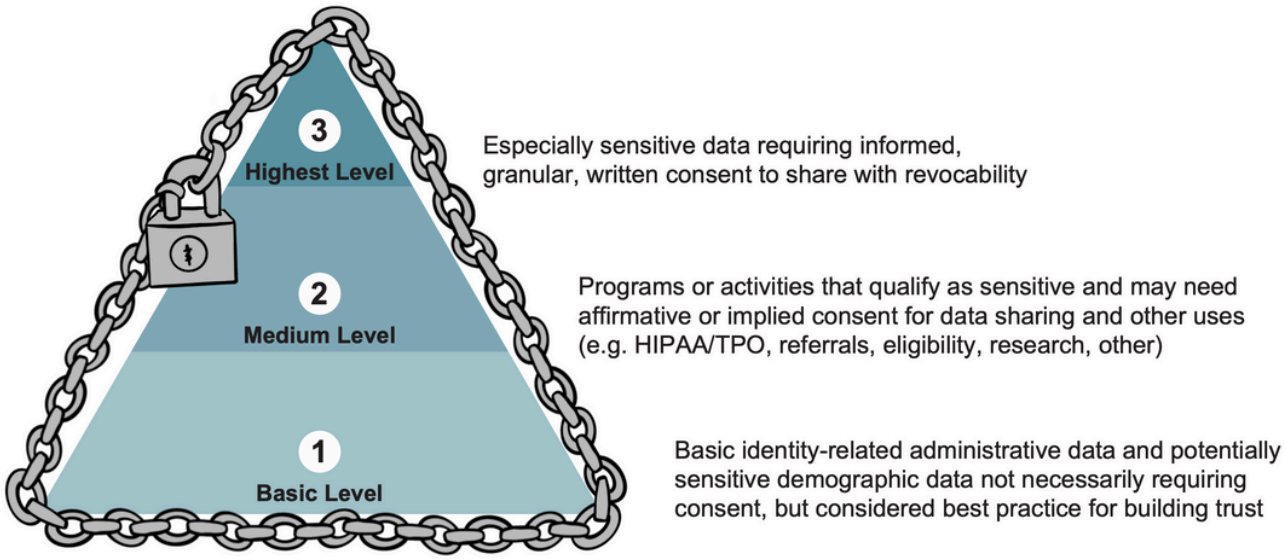
To facilitate a deeper understanding of the varied contexts in which consent plays a crucial role, participants played an engaging "Consent Bingo" game. They were given bingo-like cards containing a diverse array of programs and services spanning the realms of healthcare, human services and beyond. Participants completed their cards as they heard specific programs mentioned by the speakers.

This activity served as the foundation and catalyst for the day's discussions and ideation regarding the need for consent, or lack of requirements for consent. The diverse group of experts from healthcare and human services fields engaged in this immersive exercise, providing contextual knowledge of the broad-based complexity of managing consent. This exercise not only highlighted the pervasive nature of consent across domains, but also sparked insightful discussions around the nuances of informed decision-making, client autonomy, and the delicate balance between privacy and coordinated care.

Each square on the bingo cards represented a specific program that required careful consideration of consent requirements. From navigating the complexities of mental health treatment to facilitating cross-agency information sharing, the thought-provoking examples sparked lively discussions. Physicians, social workers, legal experts and technology specialists contributed their perspectives, illuminating the nature of consent and its implications across various domains.

The second part of this activity required the team at each table to collaborate to determine the best category for all 36 possible consents (derived from the bingo card) into one of three layers – each representing a different level, with its own requirements for sharing the consent, from broadly available to highly protected.

Through this Pyramid Segmentation exercise, participants deepened their understanding of the varying consent types and requirements. The base of the pyramid represented the most general and ethical forms of consent, such as implied consent for routine services or explicit consent for sharing non-sensitive information. As they ascended the pyramid, participants grappled with increasingly complex and regulated types of consent, including informed consent for medical procedures, parental consent for minors and advance directives for end-of-life care. At the apex lay the most stringent consent protocols, such as those governing clinical trials, organ donation and the sharing of sensitive data across jurisdictions.



Key Findings

Multidisciplinary Collaboration and Design are Critical. This exercise fostered a collaborative learning environment, enabling professionals from various disciplines to appreciate the intricate web of ethical, legal and practical considerations surrounding consent. Ultimately, this hands-on activity underscored the importance of a holistic, collaborative approach to consent management, laying the foundation for follow-on activities for the CLL.

Understandings of Legalities, Practicalities and Nuances Differ. Through this interactive experience, experts from diverse backgrounds collaborated to sort and

categorize various consent scenarios onto the appropriate pyramid segments. Spirited debates ensued as they navigated the nuanced intersections of ethical principles, legal mandates and best practices. The exercise vividly illustrated the need for a tiered, context-aware approach to consent management, highlighting the critical balance between respecting individual autonomy and facilitating seamless, coordinated-care delivery.

Panel 2: The Art of the Possible

This session focused on new policies and initiatives, with an overview and discussion about key recent policy developments, implementations and projects that will enable broader data sharing and interoperability across healthcare and human services, education and other relevant domains.

SOCI President Daniel Stein moderated this discussion. The panelists were:

- Tom Novak, ONC Senior Advisor for State Policy
- John Rancourt, Deputy Director, ONC Office of Technology
- Nichole Sweeny, JD, General Counsel and Chief Privacy Officer, CRISP

Key Findings

Collaboration among Agencies is Critical. Agencies and organizations must work together to overcome the limitations of current approaches to data exchange. Frontline agencies, such as those in human services, often rely on basic tools like email and spreadsheets to share information. Efforts should be made to include them in interoperability initiatives to ensure that their needs, requirements and other realities are taken into account.

ONC Now Includes Guiding Human Services Interoperability Standards. The ONC's statutory mission has been expanded to include responsibility and authority to guide the definition of human services interoperability standards, along with Social Drivers of Health, and to encourage their adoption by vendors and providers. Existing standards, such as FHIR, can be leveraged to facilitate interoperability and data sharing by social care systems and organizations, reducing the need for lengthy standardization processes.

ONC is Tasked with Defining Human Services Eligibility Standards. Federal and state agencies have long desired alignment in eligibility requirements for the many human

services funded by the federal Department of Health and Human Services. With CMS now positioned to pay for health-related social needs (HRSN) services through Medicare and Medicaid, alignment in eligibility requirements across the various services is needed.

Extending Existing Healthcare Standards Could Speed Social Care Standards. Clear, standardized approaches to consent are necessary to ensure individuals have control over their information and to facilitate data sharing and interoperability. Collaboration and ongoing dialogue are essential to address the complexities involved, including the specific contexts and requirements of different states and programs. Policy work is needed to determine consent requirements and facilitate multi-hop referrals in complex systems.

User-Centered Design is Key. There is an emphasis on making consent forms and processes understandable and accessible to individuals, using plain language that resonates with the intended users. Getting feedback from target populations like patients/clients, families, social workers, etc. on the language and design of consent forms is highlighted as important. Using a mix of electronic/digital and paper-based options for completing consent forms based on user needs and constraints is being discussed.

There are Implementation Challenges. The lack of funding and need for appropriations to move from pilot to full implementation was a common challenge across the projects discussed. Building technical as well as human infrastructure (social workers, navigators etc.) to properly inform and guide individuals through consent processes is difficult but crucial. Another challenge is the lack of data standards, which are needed along with greater interoperability. Leveraging existing health information exchanges was also identified as an area requiring policy/technical guidance.

Broad Applicability is the Goal. Current efforts are starting with specific use cases, such as youth behavioral health and Medicaid-related processes. But the long-term vision is to develop comprehensive, dynamic consent processes that can cover all aspects of an individual's information across social safety net services.

Interactive Activity 2: Designing A Uniform Consent Model Template

In the next activity, the table teams were asked to review and analyze two consent models we provided (California and Arlington, VA) using a Consent Consideration worksheet. Each of these models harmonize relevant legal requirements to provide a unified consent to streamline the collection and sharing of data across health and social services providers.

The stark difference between them is that California's ASCMI presents a single consent for global information sharing among named partners (with the addition of a special provision for 42 CFR Part 2 protected records), while Arlington's approach is highly granular, requiring specific election of sharing between the agency at which the authorization is completed and each named organization/provider, as well as explicit determination of the type of information to be shared. These two models also represent the breadth and wide spectrum between centrally, digitally managed versus distributed, paper-based consent.

In teams, participants explored a complex user story about a fictional family with the last name Thomson, and discussed the inherent data sharing required to better-enable coordinated care for the personas involved. Each team assessed and mapped its assigned user story, applying uniform consent model concepts, and generated recommendations to guide the design of a national uniform consent model template.

The Thomson family personas and user narratives about them have been developed and updated by SOCI since 2019. They were the first personas used to test and demonstrate a proof-of-concept for the Gravity Project closed-loop referrals in 2020, and they have been incorporated into the Gravity Project personas since 2023. These personas represent a non-nuclear family and an extended family beyond the household. The user narratives show the changes in multiple, related families' fortunes and challenges over time

Using a guided template, teams analyzed user stories and considered these questions:

1. What services are being sought or recommended for each person?
2. Which data and information will be shared, with whom and for what purpose for each person in the story?
3. Which specific consents will be needed or recommended to initiate, evaluate or sustain services?
4. Which consent template would fit best and/or how would you modify it to meet the criteria and make it equitable and operational?

The purpose of this exercise was for participants to generate general principles of disclosure and consent that would be helpful in developing successful implementations. These include whether the validity of consent may be further enhanced through operational mechanisms that provide tools for the capture, maintenance or revocation of consent; those that allow for segregation and non-reporting of individual record elements; or others that might otherwise enable granular data management.

Key Findings

Consent Should be Voluntary. Meaningful consent must be human-centered and managed with the best interests of the patient/client in mind. This includes ensuring that no one feels coerced into providing a consent to receive services. (Unrestricted consent to share is required to participate in some care-coordination programs.) Personal safety, health and agency should be key tenants of any universal consent solution.

Everyone Should Understand What They are Signing. Formal consent procedures and forms may not always result in individuals' genuine knowledge of what they have assented to. This can be for various reasons, including the use of legalese or medical jargon, complex language and overly lengthy explanations – rather than straight-forward, plain wording that is appropriate for the education level and languages understood by prospective signers. Bottom line: All the contents of the consent document should be clear and concise.

Flexibility is Fundamental. Different types of scenarios and environments call for different types of consent. This includes broad versus granular approaches to choosing who can exchange information and selecting specific data elements for sharing.

So is Revocability. Consent should not be evergreen; i.e., consumers should have the option and ability to decide they no longer wish to share some or all their personal information. Critical issues in revocability include the difference between halting all sharing, revoking sharing with certain partners, and revoking the sharing of specific data elements. Additionally, whether retrospective revocation is enforceable must be considered.

The Right Technology Needs to be Used. Capturing, storing and maintaining consent requires standards and centralized solutions with appropriate authority and resources to support consent processes, both partially and end-to-end.

Funding for Sustainably Please! While grants and alternative funding approaches have enabled consent-related pilots, there is no clear and sustainable funding stream to create and maintain the centralized operations needed for consent management that cuts across the broad array of relevant sectors, agencies and populations to be served.

The Consent Service Utility is Flexible and Extensible. The UCMT could be designed to provide a modular approach, including with standards, to accommodate most if not all consents. By examining the perspectives and feedback from diverse stakeholders and

analyzing the nuances of consent-related laws and guidelines at the federal level, the foundation is laid for universal consent models to be adapted to state laws and processes.

The Art of the Potential: Synthesizing Learning and Next Steps

The closing activity of the CLL was a facilitated discussion to share learning and hear about innovations that may impact the design, testing and implementation of a uniform consent model template. The outcomes and recommendations from this final session and insights from the CLL are incorporated into this paper. Most importantly, we identified the CSU's missing element: The UCMT, which would provide the means for jurisdictions to work from model templates to formulate their unique consent requirements, without having to start from scratch. These customized consents would enable the CSU and its commensurate technologies to manage consent computably, automatically, equitably and securely.

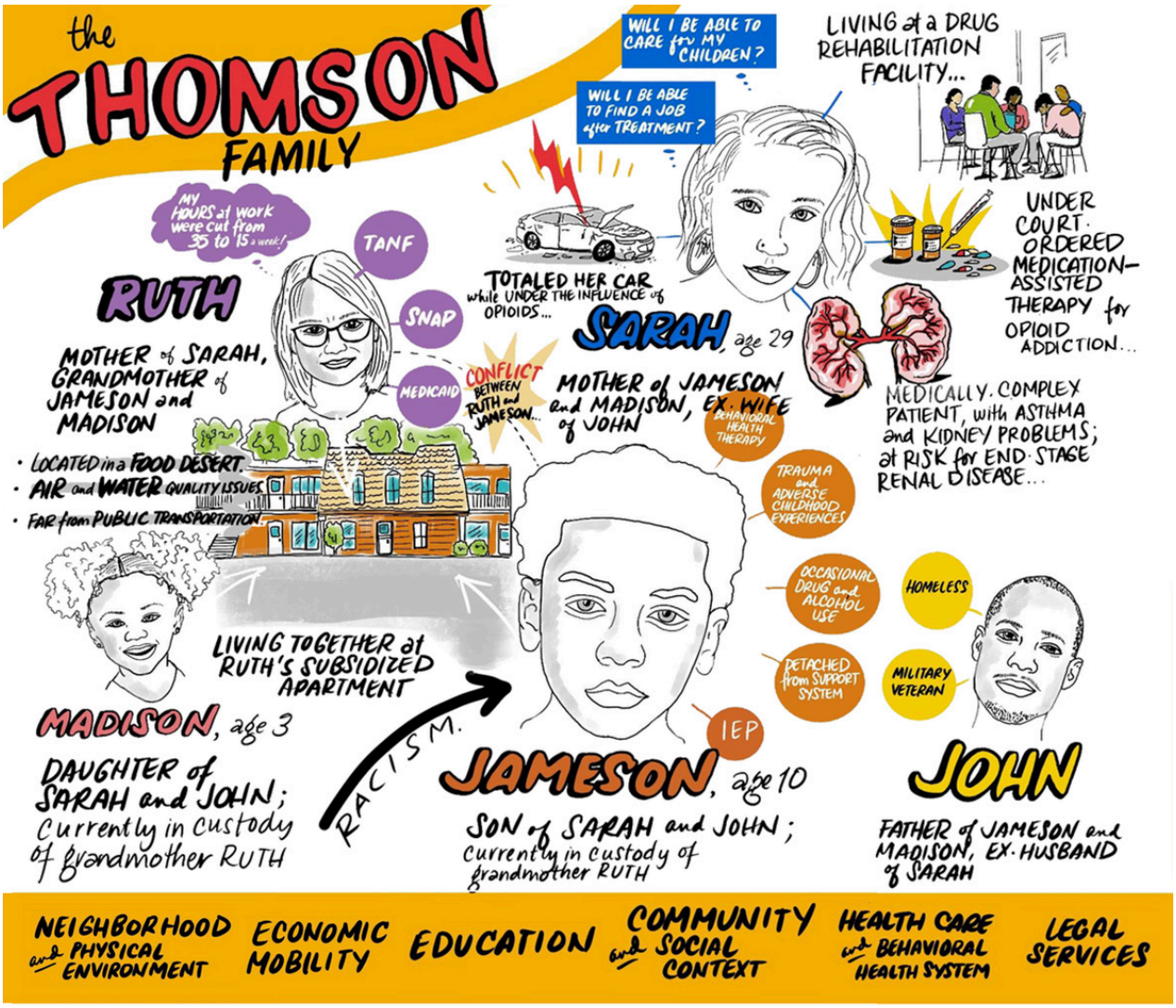
Appendix C:
2024 Consent Learning Lab Participant List And Affiliations

Consent Learning Lab Participants 2024			
First Name	Last Name	Title	Organization
Jack	Anderson	Sales Engineer	InterSystems
Chris	Alibrandi, JD	Deputy Director	Network for Public Health Law – Mid-States Region
Pooja	Babbrah	Strategy Leader	Point-of-Care Partners
Kendra	Baker	Innovation Team Lead	Interoperability Institute
Angie	Bass	Chief Strategy Officer	MiHIN & Velatura Public Benefit Corporation
Mike	Bertrand	Chief Technology Officer	Midato Health
Matt	Bishop	CEO	Open CIty Labs
Jerry	Britcher	Assistant Director / Chief Information Officer	Washington State Health Care Authority
Jason	Buckner	CIO	Manifest Medex
Hans	Buitendijk	Director, Interoperability Strategy	Oracle Health
Vadim	Cherdak	Entrepreneur, investor, fractional CTO	AI and Medical IoT, Digital Health
Charles	Curran, JD	Data Policy Consultant	Charles D. Curran Consulting LLC
Madeleine	Dwyer	Policy Analyst	Equity in Civic Technology
Esther	Dyson	Founder	Wellville
Marty	Elisco	CEO and Co-Founder	Augintel
Danielle	Friend	Director of Integration	Epic
Sue	Gallagher	Chief Innovation Officer	Children's Services Council of Broward County
Evelyn	Gallego	Founder & CEO	EMI Advisors LLC
Erica	Galvez	CEO	Manifest Medex
Matthew	Gee	Co-Founder & CEO	BrightHive
Allan	Gobbs	Venture Investor, Deeptech Entrepreneur & Educator	Consultant
Kirk	Grothe	Head of Government	InterSystems

Joel	Gruenberg	Vice President Research & Development	Interoperability Institute
Kris	Haag	Managing Director	EMI Advisors LLC
Brian	Handspicker	Chief Technology Officer	Open City Labs and Stewards of Change Institute
Helen	Hill	Principal	The Kiran Consortium Group LLC
Carole	Hussey	President	Evolv Strategy Group
Mohammad	Jafari	Senior Privacy Consultant and Integration Specialist	Independent Consultant
Eric	Jahn	Data Architect/CTO	Alexandria Consulting LLC
Lenel	James	Business Lead, Health Information Exchange and Innovation	Blue Cross Blue Shield Association
Mary-Sara	Jones	Sr Business Development Exec, Health & Human Services	Amazon Web Services
Alana	Kalinowski	Director Interoperability and Collective Impact	211/CIE San Diego
Sarah	Kang	Manager	Blue Path Health
Alan	Katz	Associate Director of Advocacy & Public Policy	Civitas Networks for Health
Sonia	Kim	Partner/Project Director	Alexandria Consulting
Julie	Klahr, JD	Attorney	Goren Cherof Doody & Ezrol, P.A.
Mary	Kratz	Executive Vice President	Interoperability Institute, LLC
Tom	Leary	Senior Vice President and Head of Government Relations	HIMSS
David	Lee	Health Policy	Leavitt Partners
Nancy	Lush	President	Patient Centric Solutions, Inc
John	Manning	CEO, Co-Founder	MayJuun
Shelley	Mannino	Vice President, Customer Affairs	Velatura Public Benefit Corporation
Kristine	McCoy, MD, MPH	Primary care and public health consultant	Two Oceans Consulting & Stewards of Change Institute
Sterling	McCullough	Market Lead - HHS / Transportation	InterSystems
Waldo	Mikels-Carrasco	Director	Center for Health Information Sharing & Innovation (CHISI) at the Illinois Public Health Institute

Tom	Novak	Senior Advisor State Policy	Office of the National Coordinator for Health IT
Eliel	Oliveria	Senior Director	Harvard Medical School. CEO, Connxus HIE
Eric	Pelletier	Executive Advisor to Management	Institut National De Santé Publique Du Québec
Charles	Purcil	CEO	Prime Physicians
David	Pyke	Technical SME	The Sequioa Project
John	Rancourt	Deputy Director	Office of Technology, Office of the National Coordinator for Health IT, U.S. Dept. HHS
Jolie	Ritzo	Vice President of Strategy and Network Engagement	Civitas Networks for Health
Carol	Robinson	Founder, CEO	Midato Health
Rick	Sage	Executive Vice President, Innovation & Standards	National Council for Prescription Drug Programs
Sumit	Sajnani	Health Information Technology Officer	State of CT
Jennifer	Searls	Executive Director	Connie HIE
Sristi	Sharma, MD	Medical Informatics Physician, Office of Deputy Director, Enterprise Data & Information Management	California Department of Health Care Services
Kendall	Stanley	Vice President of Sales and Marketing	NinePatch
Jim	StClair	Strategy Consultant	Interoperability Institute, LLC
Daniel	Stein	President	Stewards of Change Institute
Nichole	Sweeney	General Counsel and Chief Privacy Officer	Chesapeake Regional Information System for our Patients
Levette	Williams	Senior Subject Matter Expert	AEM Corporate (US Department of Education Contractor)
Jaffer	Traish	Chief Operating Officer	Findhelp
Michelle	Zancan	Senior Clinical Analyst.	Zane Networks, LLC

Appendix D:
The Thomson Family Scenario



A 10-year-old boy named Jameson has recently been placed into the child welfare system because his single mother, Sarah Thomson, was incarcerated for driving under the influence of opioids and reckless endangerment. Her car was totaled when she crashed into a light pole. As a result of her arrest, Child Protective Services placed Jameson and his 3-year-old sister, Madison, in the legal custody of Sarah's mother, Ruth, while social workers and the courts decide if either or both children will be reunited with Sarah, remain with their grandmother, or move to a foster family to await adoption.

Sarah, who is 29, was between jobs and could not afford to buy a new car. The social service professionals now working with her (primarily at the drug rehabilitation facility where she is currently living) worry that it will be difficult for her to find another job once she's out of treatment, especially in the midst of the coronavirus pandemic. They are also

concerned because, even if she finds employment, there is virtually no public transportation in the area in which she and her children have been living with her mother. Sarah is a medically complex patient with multiple chronic conditions: asthma and kidney problems that put her at risk of progressing to end-stage renal disease. She is also under court-ordered Medication Assisted Therapy for her opioid addiction.

Jameson, Madison and their mother moved into Ruth's subsidized apartment six months ago, after Sara divorced the children's father, John Thompson. He is a military veteran who is currently homeless; he provides no financial support to his ex-wife and children. The family's total income – including Ruth's – barely exceeds the federal poverty level, so they receive TANF, SNAP and Medicaid benefits. Ruth's apartment is in a rundown area of Temperance, MI, a "food desert" with little public transportation or other services. A furniture manufacturer and a large corporate farm in the area have contributed to air- and water-quality issues; several lawsuits have been filed against them alleging that their activities undermine the health of local residents.

As a result of the family's problems and Jameson's transfer to a school near his new residence, he was held back a grade, a reality that is taking an educational, emotional and social toll on him. Jameson is receiving behavioral health therapy, prescribed by Child Protective Services to address his Adverse Childhood Experiences, which include his parents' divorce, his father's complete absence, his mother's addiction and incarceration, his moves to a new community and school where he knows no one, and regular taunting by other children – and sometimes adults – related to his being biracial. (He presents as Black, like his father, and the neighborhood in which he lives is overwhelmingly White.)

In short, Jameson is traumatized. He is also dealing with new, challenging experiences such as meetings with an overloaded case manager, appearances in family court, the stress of both his parents' absence, and becoming accustomed to a new primary care-giver and residence. And, at the same time, he has been detached from his entire support system except for his grandmother, who takes two buses every day to travel for over an hour to her job cleaning hotel rooms; as a result of COVID-19, her hours there have been cut from 35 to 15 per week, resulting in a major loss of income.

Jameson has become withdrawn at school and testy with his grandmother. Since he moved in with her, he has not been regularly taking his medications or using his inhaler; as a consequence, his physical, mental, and behavioral health are deteriorating. In addition, although he has an IEP and receives behavioral health therapy, Jameson has connected with some older kids in the neighborhood and occasionally uses drugs and alcohol as a way to escape his misery and anxiety.

His new teachers see his steady devolution and provide a mandatory report to the School Assistance Team. The team then contacts his child welfare case manager, who needs to work with Jameson's primary care physician, a psychologist, teachers, foster parents and a family court to get him additional behavioral health support/services for his trauma, substance abuse and other issues.

Appendix E
Consent Consideration, Types and Usage Guidance

Considerations for Implementing Uniform Consent

Deployment of uniform consent to streamline the collection and sharing of data across healthcare and social services providers requires a harmonization of legal disclosures according to relevant jurisdictional requirements. But there are recognized general principles of disclosure and consent that will be helpful in developing successful implementations. The validity of consent may be further enhanced through operational mechanisms that provide tools for the capture, maintenance or revocation of consent (whether paper-based or digital); allow for the segregation and non-reporting of individual record elements; or that otherwise allow granular management of recipients.

General Principles	California ASCMI (Yes, No, Maybe)	Arlington VA (Yes, No, Maybe)
Has consent been freely given? Valid consent requires genuine choice, along with an absence of coercion in the circumstances in which it is obtained or detriment to the individual upon refusal. Capacity (e.g., minors) and the scope/duration of consent implied in emergency situations should also be considered.		
Is consent specific and informed? To be valid, both the specific purposes for which data will be used should be disclosed along with the identities of the organizations collecting or receiving such information. Particularly specific disclosure may be needed for uses or transfer of especially sensitive data. • For organizations collecting or receiving data, how are their identities disclosed (by category or specific name, rather than by type of organization)? • For use purposes, are the types of individual data and their uses described with precision and clarity, not merely in general terms? • Do especially sensitive data uses (Part 2, e.g.) receive more prominent disclosure and/or separate consent?		
What general protections are promised for data use or access? Are there protections provided that apply to all data, and which help prevent harm to the individual (e.g., data shared only to provide "access to social services," or other regulatory protections)? Protections can include limits on law enforcement access, cybersecurity, accountability mechanisms, and renewed consent requirements if data use changes.		
Is consent unambiguous, and has it been signaled by a clear affirmative act? Consent requires a record (paper or digital). For certain types of use or for particular recipients, boxes explaining the specific use or recipients may need to be checked by the consenting individual (and not pre-checked).		
Is the consent revocable (or does it automatically expire)? To be valid, consent should be accompanied by a representation that consent may be withdrawn to all or some data uses, along with an explanation of data uses that may still occur after revocation. If consent is time-limited, what time scales for expiration or renewal?		
Operational Considerations for Consent	California ASCMI (Yes, No, Maybe)	Arlington VA (Yes, No, Maybe)
What mechanisms capture consent? If paper forms are contextually appropriate, are there subsequent pathways to create an electronic record of consent (scanned PDF, tablet use at the point of care, Web links/QR codes)? Beyond the consent form, what other mechanisms support the consent process and how are these documented (e.g., health care provider explanation, supplemental disclosures)?		
How are comprehensibility and accessibility addressed? How is audience-appropriate comprehensibility implemented (plain English, e.g.), along with accessibility? To ensure equity, are language and other potential barriers to informed consent addressed? Do user testing and lived experience support the approach?		
What tools for ongoing individual management of data? After initial consent, what mechanisms allow for subsequent management or auditing of data recipients or consent revocation? Are specific records kept about the identities of subsequent downstream recipients for certain types of data, or capture of renewed consent for onward referral of especially sensitive data? Is the approach financially feasible? What standards ensure that data permissions or consent revocation requests are effective across relevant systems? How is the identity of individuals making such requests validated?		

The Consent Matrix Tool and Catalogue would include the universe of programs including this list which would be enhanced over time as more participants implement the CSU.

Consent Domains

1. Social Care
2. Child Welfare
3. Research
4. Public Health
5. Medicine/Clinical Health Care
6. Elementary and SecondaryEducation
7. Behavioral Health
8. Justice
9. Processes
10. Administrative and Demographic

Programs

1. Social Care
   a. Temporary Assistance (TANF)
   b. Home Visiting
   c. Disability
   d. Child Support Enforcement
   e. Housing
   f. Food and Nutrition (SNAP)
   g. Community Based Services
   h. Transportation
   i. Child Care/Head Start
   j. Domestic Violence
   k. Sensitive Demographic Information
   l. Jobs/Work
   m. Women and Infant Care (WIC)
   n. Adult Aging
   o. Refugee Resettlement

2. Child Welfare
   a. Foster Care
   b. Residential Care
   c. Kinship Care
   d. Child Protective Services
   e. Medication

3. Research

4. Public Health
   a. Population Health
   b. Reportable Conditions
   c. Policy/Research
   d. HIV/AIDs

5. Medicine/Health Care
   a. HIPAA & Care Coordination
   b. Reproductive Health
   c. Advanced Medical Directives
   d. Admissions, Discharges, Transfers (ADT)
   e. Emergency Medical Services
   f. Gender Affirming Services
   g. Clinical Trials
   h. Post Acute Care
   i. Pharmacy

6. Elementary and Secondary Education
   a. Early Intervention (IDEA part C)
   b. Attendance, Truancy, Tardiness
   c. Medical
   d. Probation
   e. Child Welfare

7. Behavioral Health
   a. Substance Use Disorder
   b. Mental Health
   c. Coordinated Care

8. Justice
   a. Courts
   b. Probation
   c. Prison/Jails
   d. Re-entry Programs

9. Processes
   a. Eligibility Determination
   b. Referral Services
   c. Wearables and Digital Health Technology

10. Administrative and Demographic

Appendix F:
Consent Taxonomy Matrix

The goal of an automated consent management solution is to allow various data systems to incorporate consent information into their business processes for data handling, such that the consent data may be understood and acted on by a data system without need for human intervention or direction. To achieve this goal, each of the various dimensions of consent must be reduced to and captured in a consistent and comprehensive manner.

The table below presents a hypothetical taxonomy for consent data:

Element	Example of Values
Consent Provided By	[Name]
Delegated Consent	[Yes/No]
Data Type/Category	Demographic Data
	Program Engagement (“known to”)
	Economic/Eligibility
	Medical/Clinical
	Behavioral/Mental Health/Addiction Disorder
	Non-Medical Case Management
Sharing Purpose(s)	Demographics/Identity Matching
	Eligibility Determination
	Case Management & Service Related
	Care Coordination (multi-program/agency)
	Program Administration (QA/QC, integrity, etc.)
	Treatment
	Research
Privacy Regulation or Regime(s)	HIPAA
	42 CFR Part 2
	FCRA (Fair Credit Reporting Act)
	FERPA (Family Educational Rights and Privacy Act)
	IRC 1603 and the Privacy Act of 1974 (IRS)
	State reproductive health information protections
	State domestic violence victims’ protections
	Etc.

Consent Requirement Level	High
	Medium
	Low
	None
Consent Scope	Specific Program/Entity
	Multiple Programs/Entities (specified)
	General Category of Providers (specific recipients undefined)
Consent Grant Date (signature)	[Date]
Consent Duration	One-Time
	Limited/Expiring
	Unlimited
Consent Renewal Due Data	[Date]
Client Notice Required	[YES/NO]
Data Sharing Is	Required by law or regulation
	Always allowed
	Allow for limited purposes/users
	Allowed with consent
	Prohibited

This hypothetical, partial list of potential consent elements hopefully demonstrates the complexity of capturing the various dimensions of consent. It is also important to remember that even within a program or data system, different types of information may be subject to different levels of privacy requirements. For instance, demographic information may have a low consent threshold, while the threshold for behavioral health data may very high – and if the demographic and behavioral health data are being shared together, then best practice would likely require the application of the higher threshold.

The taxonomy must provide:

- Granularity – the ability to capture and convey a wide range information with precision for application at the source, data cohort, or individual data-element level,
- Flexibility – the ability to be applied to a wide range of programs, systems and purposes.
- Elasticity – the ability to be modified and expanded to include additional information, responses and uses without disrupting the existing scheme or functionality.

Appendix G:
Consent Template Examples:
1) ASMCI California Original Form
2) ASMCI Version 2.0
3) Arlington County, Virginia

Authorization to Share Confidential Medi-Cal Information (ASCMI)

Version 1.0 [Pilot]

December 2022

Disclaimer: The ASCMI Form is intended to be used solely by ASCMI Pilot participants. DHCS makes no representation about the suitability of this form for uses outside of the ASCMI Pilot. The ASCMI Form, including attachments, are subject to change.

First Name	Last Name	Date of Birth	
Mailing Address	City	State	Zip Code
Residential Address	City	State	Zip Code
Phone Number(s)	Email	Beneficiary Identification Card (BIC)	

By signing this form, you authorize certain organizations and individuals to use and share your health and other confidential information for the purposes described in section 1.

1. Purposes

By signing, you authorize your health and other confidential information to be shared only to:

(a) Provide you with, refer you to, or help you access healthcare treatment, benefits, programs, social services, case management, community resources, and other supports ("Services") to meet your needs.

(b) Identify, support, coordinate, improve, and arrange payment for Services that may be provided to you.

(c) Help Medi-Cal provide better care through evaluation, reporting, and population health management.

2. Types of Your Information that You Authorize to be Shared

By signing, you authorize the below types of health and other confidential information about you to be shared only for the purposes stated above.

(a) Protected health information (PHI), including information regarding your health care, medical history, lab test results, and current or future conditions and treatments.

Authorization to Share Confidential Medi-Cal Information (ASCMI)

(b) Mental health information, including current and past diagnoses and treatments of your mental health conditions. This does not include psychotherapy notes, which are only shared if you separately consent.

(c) Substance use disorder information, including your current and past alcohol or drug use diagnoses, medications, treatment, lab tests, trauma history, facility discharges. This includes substance use disorder information about you that comes from a substance/alcohol use disorder provider subject to federal substance use confidentiality regulations (42 C.F.R. Part 2) if you check the box at the end of this form.

(d) Individualized Education Programs, and other information about social services provided in schools.

(e) Medi-Cal eligibility/enrollment information, which includes income and certain other demographic and geographic information pertaining to your eligibility for Services and benefits.

(f) Housing/homelessness information, including your housing status, history, and supports.

(g) Limited criminal justice information, including booking data, dates and location of incarceration, and supervision status. Your consent does not apply to your criminal history, charges, and immigration status.

3. Sources and Recipients of Your Information

By signing, you agree to allow a health information exchange or community information exchange ("HIE/CIE") facilitate the exchange of your health and other confidential information with and between your care partners from which you have received, are receiving, or will receive benefits, treatment, or services (""Your Care Partners"). Information may be shared only for the purposes in part 1. Your Care Partners may include the following:

(a) Healthcare providers, such as hospitals, clinics, physicians, pharmacies, and behavioral health providers.

(b) Managed care plans (MCPs), which administer Medi-Cal benefits and pay for services you receive under Medi-Cal.

(c) Certain community-based organizations (CBOs) that must comply with federal health care privacy laws, including some medically tailored meal providers, housing providers, and asthma remediation providers.

Authorization to Share Confidential Medi-Cal Information (ASCMI)

(d) School-based providers of health or social services, such as nurses, social workers, and counselors.
(e) State health agencies, specifically, the California Departments of Health Care Services, Public Health, Social Services, and Developmental Services.
(f) County agencies, including mental health plans, human/social services or welfare departments, drug Medi-Cal organized delivery systems, and health and public health departments.
(g) Providers & case managers at correctional facilities, such as those at jails, prisons, and youth correctional facilities, only for the purposes in part 1 of this form. You do not consent to the use of your information for criminal investigations or prosecutions, sentencing, parole or probation monitoring, immigration enforcement, or family court proceedings.

Your Care Partners and their contractors agree to obey all applicable laws protecting your information.

4. Expiration, Revocation, or Change of This Form

Once signed, this form will be effective until the first of the following occurs:

(a) 24 months from the date on which you were last enrolled in Medi-Cal;
(b) you revoke this form; or
(c) you make any change to this form, and the modified form becomes effective.

5. Your Rights

You understand that:

(a) you can revoke this form at any time through the consent management service portal or by sending a revocation request signed by you or your representative to the HIE/CIE. ;
(b) a revocation is effective when received but may not apply to information already shared based on your past executed form, which may not be recalled or deleted;
(c) you may decline to sign this form and doing so will not affect your treatment or care, your eligibility for or ability to receive Services, or the payment for Services;
(d) you have a right to receive a copy of this form;
(e) the information you authorize for release could be re-disclosed by Your Care Partners, but only in compliance with this form and applicable law; and
(f) you may obtain a list of Your Care Partners to which your information has been disclosed by contacting the HIE/CIE.

Authorization to Share Confidential Medi-Cal Information (ASCMI)

Each of these rights extend to your representative if authorized by you under applicable law.

6. Sharing Information Without Your Consent

You understand that even if you do not sign this form, under federal and state privacy laws some of Your Care Partners may share your confidential information for treatment, payment, and other purposes, but providers subject to federal substance use confidentiality laws generally may not share your substance use disorder information without your consent.

7. Authorization

By signing this form, I authorize certain organizations and individuals to use and share my health and other confidential information for purposes described in part 1 of this form. Also, if I voluntarily include my phone number above, I consent to the receipt of texts or calls to communicate with me about my consent choices and how my information may be shared (standard message and data rates may apply).

☐ By checking this box, I also authorize the disclosure of substance use disorder information about me that comes from providers subject to federal substance use confidentiality regulations (42 C.F.R. Part 2).

If you are signing on your own behalf, fill out the 1st line. If you are signing on behalf of someone else, fill out the 2nd line. If you are signing on behalf of a minor aged 12-17, the minor should fill out the 1st line and you should fill out the 2nd line.

Beneficiary's Name	Beneficiary's Signature	Date (mm/dd/yyyy)
Representative's Name	Representative's Signature	Date (mm/dd/yyyy)

New Form 2024:

Authorization to Share California Member Information (ASCMI) Form (Version 2.0)

This document is a dynamic release of information authorization form, meaning specific components of the form will differ depending on the individual signing the form.

CalAIM AB 133 Version	Non-CalAIM AB 133 Version
Applies to: 1. Individuals enrolled in a managed care plan within Medi-Cal; 2. Individuals receiving behavioral health services under Medi-Cal; and 3. Justice-involved individuals that qualify for pre-release Medi-Cal benefits. All federal privacy laws apply but some state privacy laws are waived.	Applies to all individuals who do not meet the criteria for the CalAIM AB 133 Version as described on the left. All federal and state privacy laws apply

Authorization to Share California Member Information (ASCMI) Form

Fillable Fields

- First Name
- Last Name
- DOB
- Mailing Address, City/State, Zip Code
- Residential Address, City/State, Zip Code
- Phone #
- Email
- Medi-Cal Client Index Number (CIN) (as applicable)

1. PURPOSE OF FORM

[Medi-Cal]is asking for your authorization to allow sharing of your health information and other personal information ("information"). If you agree, your information will be shared so that individuals and organizations that provide you with benefits, treatments, and/or services ("care partners") will be able to:

- Identify and connect you to programs, services, or resources that could benefit your health and wellbeing
- Better provide you with and coordinate your care
- Help [Medi-Cal] provide better care through evaluation, reporting, and population health management

This Form does not indicate your consent to the use of your information for civil, administrative, or criminal investigations, proceedings, or prosecutions, sentencing, parole or probation monitoring, immigration enforcement, or family court proceedings.

Signing this form is optional and is your choice. If you choose not to sign the Form, it will not change your eligibility for benefits or ability to receive care or services. However, if you sign the Form, your care partner may have better access to your information and be better able to coordinate your care and help you get connected to other services quicker.

What is still shared if I do not sign? State and federal laws already allow for some sharing of information. For example, health care organizations can share your health information to treat you, obtain payment, and run their programs.

Authorization to Share California Member Information (ASCMI) Form

Fillable Fields

- First Name
- Last Name
- DOB
- Mailing Address, City/State, Zip Code
- Residential Address, City/State, Zip Code
- Phone #
- Email
- Medi-Cal Client Index Number (CIN) (as applicable)

2. TYPES OF INFORMATION

What will be shared? By signing, you authorize the below types of health and other confidential information about you to be shared only for the purposes stated above:

a. Physical and behavioral health status and treatment information
b. Housing, food, employment and income status, history, and supports
c. Limited criminal justice information, including booking data, dates and location of incarceration, and supervision status.

CalAIM AB 133 Version	Non-CalAIM AB 133 Version
You may limit sharing of substance use disorder (SUD) information that is protected by 42 C.F.R. Part 2 in the special permission section below. You may also limit the sharing of abortion-related information to care partners outside of the state of California, per AB 352, in the special permission section below.	You may limit sharing of the following types of information in the special permission section below: • SUD information that is protected by 42 C.F.R. Part 2 and California State law • Mental health information • HIV test results • Genetic test results You may also limit the sharing of abortion-related information to care partners outside of the state of California, per AB 352, in the special permission section below.

3. SOURCES AND RECIPIENTS OF YOUR INFORMATION

Who will my information be shared with? Your information will be shared between past, current, and future care partners, which may include:

a.Physical and mental health providers
b.SUD providers
c.Managed care and behavioral health plans
d.Certain community-based organizations (CBOs), such as foodbanks
e.School-based providers
f.State health agencies
g.County agencies
h.Correctional facility providers and case managers

4. EXPIRATION, REVOCATION, AND MODIFICATION OF THIS FORM

CalAIM AB 133 Version	Non-CalAIM AB 133 Version
For how long am I authorizing my information to be shared? This authorization will remain in effect for a period of two years from the date of your signature, or until you change or revoke your authorization.	**For how long am I authorizing my information to be shared?** This authorization will remain in effect for a period of one year from the date of your signature, or until you change or revoke your authorization.

5. YOUR RIGHTS

I have the right to:

a.Refuse to sign this Form
b.Receive a copy of this Form
c.Obtain a list of my care partners to which my information has been disclosed by contacting [Organization Name]

6. Special Permissions

CalAIM AB 133 Version	Non-CalAIM AB 133 Version
We need your special permission to share information about SUD that is protected by 42 C.F.R. Part 2. If you give permission, this information can be shared with [Medi-Cal], as well as the types of organizations listed above, to coordinate your care and services. Even if these do not apply to you today, giving permission now can help make sure your information can be shared in the future if needed. **SUD Information Protected by 42 C.F.R. Part 2** I give permission to share information about my past, present and future SUD information that is protected by 42 C.F.R. Part 2. ☐ Yes ☐ No **Abortion Information Protected by AB 352** We need your special permission to share information related to you seeking, obtaining, performing, or assisting in the performance of an abortion with Care Partners outside the state of California. If you give your permission, abortion-related information may be shared with an out-of-state care partner only for the purposes of coordinating your care and services. I give permission to share past, present, and future abortion-related information with Care Partners outside the state of California. ☐ Yes ☐ No	We need your special permission to share information about SUD that is protected by 42 C.F.R. Part 2 and California state law, mental health treatment, HIV test results, and genetic test results. If you give permission, this information could be shared with [Medi-Cal], as well as the types of organizations listed above, to coordinate your care and services. Even if these do not apply to you today, giving permission now can help make sure your information can be shared in the future if needed. **SUD Information Protected by 42 C.F.R. Part 2 and California state law** I give permission to share information about my past, present and future SUD information that is protected by 42 C.F.R. Part 2. ☐ Yes ☐ No **Mental Health Treatment** I give permission to share information about my past, present and future mental health information. ☐ Yes ☐ No **HIV Test Results** I give permission to share information about my past, present and future HIV test results. ☐ Yes ☐ No **Genetic Test Results** I give permission to share information about my past, present and future genetic test results. ☐ Yes ☐ No **Abortionn Information Protected by AB 352** We need your special permission to share information related to you seeking, obtaining, performing, or assisting in the performance of an abortion with Care Partners outside the state of California. If you give your permission, abortion-related information may be shared with an out-of-state care partner only for the purposes of coordinating your care and services. I give permission to share past, present, and future abortion-related information with Care Partners outside the state of California. ☐ Yes ☐ No

7. Your Authorization

By signing this Form, I understand and agree that:

- Certain organizations and individuals may use and share my health and other confidential information for purposes described in section 1 of this Form.
- My information could be re-disclosed by those who receive it and may no longer be protected by federal privacy law.
- If I voluntarily include my phone number above, I consent to the receipt of texts or calls to communicate with me about my consent choices and how my information may be shared (and that standard message and data rates may apply).

If you are signing on your own behalf, fill out the 1st line. If you are signing on behalf of someone else, fill out the 2nd line. If you are signing on behalf of a minor aged 12-17, the minor should fill out the 1st line and you should fill out the 2nd line. [Add instructions for providing documentation]

Fillable Fields
• Name | Signature | Date (mm/dd/yyyy)
• Representative's Name | Representative's Signature | Date (mm/dd/yyyy)

ARLINGTON COUNTY
SHARED AUTHORIZATION TO USE AND EXCHANGE INFORMATION

Individual's Legal Name:		Date:	
Individual's Date of Birth:		SSN Or Client ID # (optional):	

I want the confidential information indicated below to be shared to facilitate effective service delivery. I understand only the minimum necessary information will be shared with staff who have a need to know. I understand that my treatment, payment, enrollment or eligibility for benefits will not be conditioned on my signing this authorization form. (Mark all that apply.)

☐Y	☐N	**All of the Below**			
☐Y	☐N	Benefits/Services Needed, Planned, and/or Received	☐Y	☐N	Medical Diagnoses, History, and Records
☐Y	☐N	Program Participation & Case Worker	☐Y	☐N	Mental Health Diagnoses, History, and Records
☐Y	☐N	Demographics and Family Information	☐Y	☐N	Substance Use Diagnoses, History, and Records
☐Y	☐N	Crisis Management Needs	☐Y	☐N	Employment History/Records
☐Y	☐N	Financial Information	☐Y	☐N	Educational History/Records
☐Y	☐N	Rental/Housing Information	☐Y	☐N	Criminal Justice History/Records
☐Y	☐N	Other:	☐Y	☐N	Military History/Records
☐Y	☐N	Other:	☐Y	☐N	Other:

This information can be: ☐ Exchanged ☐ Disclosed (Sent Only)

This information can be shared in these format(s): ☐ Electronic (e-mail/fax/web) ☐ Written ☐ Spoken

This information can be shared for the following purposes only:

☐ Coordination of services, referral, and treatment ☐ Other:

This authorization is valid until:

☐ Date (within 1 year of date signed) ☐ Event (describe)

☐ Limit to a single disclosure – (explain)

I authorize the staff of the entities checked below to share information among themselves as outlined above necessary for the effective delivery of services.

Multi-Service			**Housing and Shelter**		
☐Y	☐N	Arlington County Department of Human Services	☐Y	☐N	A-SPAN (Arlington Street People's Assistance Network)
☐Y	☐N	Arlington County Public Schools	☐Y	☐N	Volunteers of America
☐Y	☐N	Northern Virginia Family Service	☐Y	☐N	Bridges to Independence
☐Y	☐N		☐Y	☐N	AHC Inc.
Health			☐Y	☐N	Arlington Partnership for Affordable Housing
☐Y	☐N	Arlington Free Clinic	☐Y	☐N	Wesley Housing Development Corporation
☐Y	☐N	Arlington Pediatric Center	☐Y	☐N	Wesley Property Management
☐Y	☐N	Neighborhood Health	☐Y	☐N	S.L. Nusbaum Realty Company
☐Y	☐N	Virginia Hospital Center	☐Y	☐N	AHC Management
Basic Needs			**Basic Needs**		
☐Y	☐N	Arlington THRIVE	☐Y	☐N	Arlington County Department of Parks & Recreation
☐Y	☐N	AFAC (Arlington Food Assistance Center)	☐Y	☐N	Food for Others

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Individual's Legal Name:		Date:	
Individual's Date of Birth:		SSN Or Client ID # (optional):	

Legal				Behavioral Health		
☐Y	☐ N	Just Neighbors		☐Y	☐ N	Northern Virginia Mental Health Institute
☐Y	☐ N	Offender Aid and Restoration		☐Y	☐ N	Residential Program Center Detox
☐Y	☐ N	Arlington Alcohol Action Safety Program		☐Y	☐ N	Community Residences
☐Y	☐ N	Arlington County Circuit Court		☐Y	☐ N	Fellowship Health Resources
☐Y	☐ N	Arlington Juvenile and Domestic Relations Court		☐Y	☐ N	Early Recovery
☐Y	☐ N	District 10 Probation and Parole		☐Y	☐ N	Phoenix House
☐Y	☐ N	Arlington County Sherriff's Pre-Trial Program		☐Y	☐ N	Demeter House
☐Y	☐ N	Fairfax County General District Court		**Other (specify organizations below)**		
☐Y	☐ N	United States Probation Office – Eastern District of VA		☐Y	☐ N	
☐Y	☐ N	Friends of Guest House		☐Y	☐ N	
Other (specify organizations below)				☐Y	☐ N	
☐Y	☐ N			☐Y	☐ N	
☐Y	☐ N			☐Y	☐ N	

I understand that my records are protected by Federal, State, and/or Local confidentiality laws and regulations and that they cannot be disclosed without my written consent unless otherwise provided for in the laws and regulations. I also understand that I may revoke this authorization at any time by written notification. Revocation will not apply to records already furnished in reliance upon this authorization.

I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules.

I acknowledge that the information to be released was explained to me and that this consent is given of my own free will.

Signatures of Individual and/or Substitute Decision Maker Authorizing Disclosure:

Individual's Signature:		Date:	
SDM's Signature:		Date:	
Printed Name of Person Authorizing Disclosure (if not client/individual)			
Person Authorizing Disclosure is:	☐ Parent of Minor ☐Guardian	☐ Power of Attorney (specify type):	☐ Other:

Printed Name, Title, and Organization of Staff Completing and Explaining Form:

	Arlington County Department of Human Services

Signature of Staff Completing and Explaining Form:		Date:	
This form was interpreted prior to signature into:	☐ N.A. ☐ Spanish	☐ Other:	

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