The Office of the National Coordinator for Health Information Technology

Privacy and Security Framework for Patient-Centered Outcomes Research (PCOR)

ENABLING BASIC CHOICE FOR RESEARCH CONSENT

July 2020

Table of Contents

1.0 Preface and Introduction 1
1.1 Definition of Basic Choice 1
1.2 In Scope 2
1.3 Out of Scope 2
2.0 Communities of Interest 2
3.0 Basic Choice Use Case Assumptions 4
4.0 Preconditions 4
5.0 Post Conditions 4
6.0 Research Consent Scenarios 4
6.1 Consent Scenario 1 – Participation in Research Study with Revocation of Consent 5
6.2 Consent Scenario 2 Minor Genetic Research 13
6.3 Consent Scenario 3 Mobile App Study 21
6.4 Consent Scenario 4 Translational Research 29
7.0 High Level Business Issues and Obstacles 38
8.0 Dataset Considerations 38
8.1 Core Consent Directive Data Requirements 38
8.2 Consent Document Exchange Datasets 46
9.0 Candidate Standards for Consideration 48
9.1 Candidate Standards for Syntax 48
9.2 Candidate Standards for Vocabulary 49
10.0 Appendices 50
10.1 Appendix A: Related Use Cases and Specifications 50
10.2 Appendix B: References 51
10.3 Appendix C: Glossary 54

1.0 Preface and Introduction

The Basic Choice Use Case outlined in this document was produced by the Privacy and Security Framework for Patient-Centered Outcomes Research (PCOR) project. This project was funded by the Patient-Centered Outcomes Research Trust Fund that is overseen by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The focus of the Privacy and Security Framework for PCOR project was to develop tools and resources that address the privacy and security-related legal and policy issues that affect use of data for various types of PCOR. This work aimed to support sharing of patient data and organizational efforts to comply with laws or policies that require the capture of patient consent, and compliance with that consent. Importantly, patient control over the use and disclosure of his or her electronic health information may be better supported by moving away from paper forms and toward an interoperable, electronic, and auditable consent process.

This document defines the interoperability requirements for health care data exchange that uses a basic choice consent model. [1] In this guide, the granular choice use case is framed through consent scenarios. Each consent scenario is a comprehensive description of the actors, interactions, activities, and requirements associated with the information exchange. It is a prototypical sequence of interactions in business collaboration or in an application context. This guide includes information about the:

- Operational context for the data exchange,
- Affected stakeholders,
- Information flows that must be supported, and
- Types of data involved and their required specifications for data exchange.

This guide can support the development of implementation guides and tools that lead to consistent and reliable adoption of standards that enable patient choice of how and when their health data is shared.

1.1 Definition of Basic Choice

Basic choice concerns the decision to opt-in or opt-out of sharing and accessing of the patient's electronic health information for treatment, payment, and health care operations purposes, even though the Health Insurance Portability and Accountability Act (HIPAA) does not require a patient consent directive to exchange data in many circumstances. [2] The concept of a basic choice is extended in these consent scenarios to include the sharing of information for research purposes, which is outside the scope of HIPAA. As researchers and research data networks begin to integrate with healthcare provider communities, there is an increasing use of data from electronic health records (EHR) and other forms of health information technology. Therefore, it is increasingly important to electronically capture, maintain, identify, and communicate a patient's privacy consent directive. Currently, consent for research participation is often obtained on a paper form. For purposes of these consent scenarios, the consent to participate in a research study is assumed to join the consent to share research data.

[1] This document reflects the environment and technical capabilities that were current at the time this project was active.

[2] https://www.healthit.gov/sites/default/files/exchange_treatment.pdf

1.2 In Scope

- Semantic understanding of a basic choice for research consent decision and the corresponding information that comprises a basic privacy consent directive
- Demonstration of the use of computable consent to enable privacy policy implementation and information access controls

1.3 Out of Scope

- The exact methods through which consent is captured (i.e., whether consent is captured ahead of time via a patient portal or in-office using a tablet)
- The user interface presented to the patient at the time that consent is captured
- Mechanisms for managing a research consent directive once supplied
- Organizational policies surrounding retroactivity (i.e., how to respond when a patient changes their research consent directive to "Do not share")
    - Organizational policies regarding subsequent restrictions on future use
- Mechanisms to update research consent directives
    - Maintenance and updating of consent repositories and registries

2.0 Communities of Interest

Table 1: Communities of Interest

Stakeholders / Communities of Interest	Description
Healthcare Providers	Healthcare providers with patient care responsibilities including physicians, advanced practice nurses, physician assistants, nurses, psychologists, emergency care providers, home health providers, definitive care providers, pharmacists, and other personnel involved in patient care.
Healthcare Organizations	Organizations that are engaged in or support the delivery of healthcare including hospitals, ambulatory centers, provider practices, integrated delivery networks, community health agencies, and rehabilitation centers. They can also include specialty areas such as behavioral health organizations, dental organizations, cardiology, radiology, labs, etc. The requirements for these specialty areas may vary depending on laws, regulations, and other business workflow needs. These organizations query data for various purposes and provide data for others to query.
Government Agencies	Federal, state, local agencies, and other government organizations that deliver, regulate, or provide funding for health and health care.
Data Standards Organizations	Organizations, whose purpose is to define, harmonize, and integrate standards that will meet clinical and business needs for sharing information among organizations and systems.

Stakeholders / Communities of Interest	Description
Health Information Exchange (HIE)/ Health Information Organization (HIO)	Health Information Exchanges (HIEs) and Health Information Organizations (HIOs) that exchange healthcare information electronically across organizations within a region, community, or hospital system, including Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs).
Health Information Technology (IT) Developers – EHR/ PHR/Third party application developers	Vendors that provide specific health IT solutions such as software applications and software services. These suppliers may include developers, providers, resellers, operators, the innovation community, and others who may provide these or similar capabilities. These organizations provide healthcare solutions such as EHR, patient health record (PHR) solutions, and other software applications and services. Examples include: integration vendors, data providers, medical device vendors, release of information (ROI) vendors, RMMS (Remote Monitoring Management System) vendors, diagnostic imaging service providers, clinical order system supply vendors, transcription service vendors, clearinghouses, drug knowledge suppliers, network infrastructure providers, clinical decision support (CDS) resource systems, practice-based registry system suppliers, public health registry systems, immunization information system providers, clinical genetic database/repository system vendors, health care record banking, etc.
Privacy and Security Experts	Consumer/patient and technology experts who represent privacy and security interests of the public or specific organizations.
Patients	Members of the public who receive healthcare services from ambulatory, emergency department, physician's office, and/or a public health agency/department.
Patient Advocates	Patient advocates who act as liaisons between a patient, healthcare provider(s), and research institutions, including disease-specific health groups.
Federal Demonstration and Pilot Projects	Selected communities of groups who have received federal funding through the ONC to build and strengthen their health IT infrastructure and exchange capabilities to improve care coordination, increase the quality of care, and slow the growth of health care spending.
Public Health Agencies	Public Health Agencies who query data for public health purposes and provide data for others to query.
Researchers	Organizations and groups that conduct health care research, including academic researchers, commercial researchers, and government research organizations.

3.0 Basic Choice Use Case Assumptions

- The requirements of the use case can be implemented in a variety of architectures
- Researchers are aware of and comply with the federal and legal requirements regarding consent
- Electronic systems have the capability to manage and update consent registries/repositories
- Electronic service information is known to all systems involved in the exchange
- All parties in the exchange comply with applicable privacy and security rules
    - Policy is in place for handling missing or not yet recorded patient preferences for data sharing
    - All parties comply with patient privacy preferences and subsequent handling instructions unless law requires otherwise; for example, a subpoena or a search warrant
- Disclosures are appropriately updated in the system to be reflected in accounting for disclosures that may be requested by the patient
- Requesting entity is verified and authorized to conduct a query for patient data
- Appropriate security audit mechanisms are in place
- Appropriate methods for capturing consent are in place
- Appropriate methods for sending acknowledgments for receiving of data are in place
- Appropriate methods for storing data and consent information are in place

4.0 Preconditions

- Mechanisms are in place for handling missing or not yet recorded patient preferences for data sharing
- Mechanisms are in place for systems having patient data to enforce the appropriate legal and policy requirements
- Mechanisms are in place to comply with research consent directives and subsequent handling instructions

5.0 Post Conditions

- Receiving system complies with ongoing obligations
- Sending and receiving systems have recorded the transactions in their security audit records

6.0 Research Consent Scenarios

- Research consent is a broad term used to describe one or more documents that enable participation in a research study and exchange of health information in a research setting. Federal laws prescribe the use and content of these documents. Federal laws that govern this type of exchange and their corresponding consent-related documents are described in the table below

Table 1: Common Federal Laws Governing Research Consent

Federal Law	Document	Purpose
Federal Policy for the Protection of Human Subjects (Common Rule)	Informed Consent	To involve a human being as a subject in specified research
	Minor Assent	Obtains a child's affirmative agreement to participate in research (does not negate the need for Informed Consent)
Health Insurance Portability and Accountability Act of 1996 (HIPAA)	Authorization	For the use or disclosure of protected health information
Food and Drug Administration Protection of Human Subjects	Informed Consent	To involve a human being as a subject in specified research

Each scenario presented below illustrates the exchange of one or more of the documents listed in the table above. Exchange is accomplished by one of two methods: exchange of the required components that make a consent valid under federal law or an assertion stating that consent has been properly given and recorded. An assertion is generally exchanged pursuant to an overarching arrangement (Memorandum of Understanding (MOU), contract, Rules of Engagement) between organizations where the burden of proof of consent is on the asserting organization. Contracts generally mandate that the asserting organization retains the consent indefinitely or produces the consent when needed by another organization in a timely manner.

6.1 Consent Scenario 1 – Participation in Research Study with Revocation of Consent

Table 3 below summarizes the key components represented in Scenario 1 – Participation in Research Study with Revocation of Consent. This consent scenario is split into three parts; each part illustrates exchange of some type of consent or consent derivative. The compound authorization used in this story is a combination of Common Rule Informed Consent and HIPAA Authorization. Compound authorizations are regulated by HIPAA and include a HIPAA Authorization combined with another type of written permission allowable under law (See §164.508(b)(3)).

This consent scenario incorporates privacy preserving technologies[3] enabling patients to set parameters for secondary use of their data. These technologies also allow patients to track how their information is used (for provenance and accounting of disclosures), enable compensation for the use of data, and re-contact.

[3] Set of cryptographic protocols used for the distributed computation of a function over distributed inputs without revealing additional information about the inputs.

Table 2: Scenario 1 Key Components

Data exchanged:	Part 1: Metadata indicating consent to re-contact; de-identified data Part 2: Compound authorization (from research consortium to researcher); contact information Part 3: Metadata indicating revocation of HIPAA patient authorization (from local clinic to research consortium
Other notable elements:	Use of privacy-preserving technologies Revocation of consent

6.1.1 Part 1: Alice Consents to Participation in a Study Via Tablet

Alice goes to a clinic that is affiliated with a large research consortium for routine health care. As part of her intake, she is asked whether she is interested in participating in a study of heart disease risk factors among certain populations. Staff members explain that in order to determine her eligibility she will be asked a series of questions presented to her on a tablet. They also explain that she may log into her patient portal at any time to change her consent settings. Alice is led through a series of questions; she is determined eligible for the study. The consent also asks if she would like to be re-contacted for participation in other studies for which she would qualify. She consents to be re-contacted. She signs the tablet indicating her consent to participate in the study and her authorization for release of contact information to interested researchers. Her compound authorization is stored locally at the clinic.

The following is sent by the clinic to the research consortium:

- Alice's de-identified data
- Alice's consent metadata indicating her consent to re-contact

The randomly generated identifying code linking her de-identified data to her medical record and contact information is also stored locally at the clinic.

Figure 1: Sequence Diagram for Consent Scenario 1 Part 1: Alice Consents to Participation in a Study Via Tablet

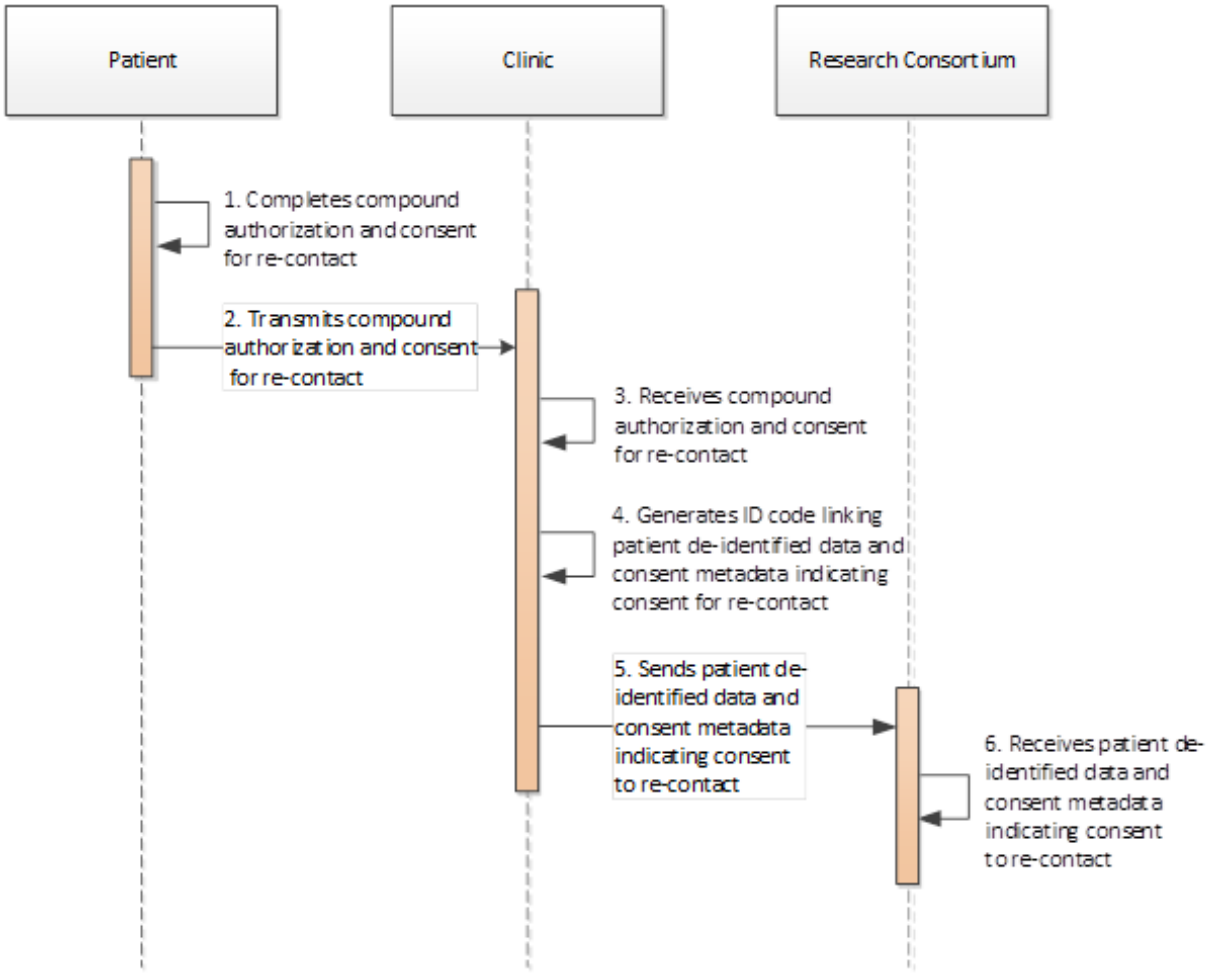


Table 3: Base Flow of Consent Scenario 1 Part 1: Alice Consents to Participation in a Study Via Tablet

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Patient	Data Source	Completes compound authorization and consent for re-contact	Compound authorization and consent for re-contact	Compound authorization and consent for re-contact	System
2	Patient	Data Source	Transmits compound authorization and consent for re-contact	Compound authorization and consent for re-contact	Compound authorization and consent for re-contact	Information Interchange
3	Clinic	Data Receiver	Receives compound authorization and consent for re-contact	Compound authorization and consent for re-contact	Compound authorization and consent for re-contact	Information Interchange

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
4	Clinic	Data Receiver	Generates ID code linking patient de-identified data and consent metadata indicating consent for re-contact	Compound authorization and consent for re-contact	Patient de-identified data and consent metadata	System
5	Clinic	Data Source	Sends patient de-identified data and consent metadata indicating consent for re-contact	Patient de-identified data and consent metadata	Patient de-identified data and consent metadata	Information Interchange
6	Research Consortium	Data Receiver	Receives patient de-identified data and consent metadata indicating consent for re-contact	Patient de-identified data and consent metadata	End Flow	Information Interchange

Table 4: System Requirements of Consent Scenario 1 Part 1: Alice Consents to Participation in a Study Via Tablet

System	System Requirement
Patient	Completes compound authorization and consent for re-contact
Clinic	Generates ID code linking patient de-identified data and consent metadata indicating consent for re-contact

6.1.2 Part 2: An Outside Researcher Contacts Alice Regarding Participation in a New Study

With separate Institutional Review Board (IRB) approval, a researcher outside of the research consortium queries de-identified data held by the research consortium and determines there are 3,500 potential participants for this study. Of these potential participants, collected metadata indicates a positive consent for re-contact for 3,000 individuals, including Alice. The outside researcher's IRB approves continuation of the study and re-contact of potential participants conditioned upon receiving the patients' original compound authorization. The researcher requests Alice's compound authorization and her contact information from the research consortium. The research consortium receives the request and requests that the clinic send Alice's compound authorization and contact information to the researcher. The clinic uses a randomly generated identifying code to relink her de-identified data to her medical record. Before sending Alice's contact information to the researcher the clinic confirms that her compound authorization permits sharing contact information. The clinic sends Alice's compound authorization and contact information to the researcher. The researcher contacts Alice regarding participation in the study.

Figure 2: Sequence Diagram for Consent Scenario 1 Part 2: An Outside Researcher Contacts Alice Regarding Participation in A New Study

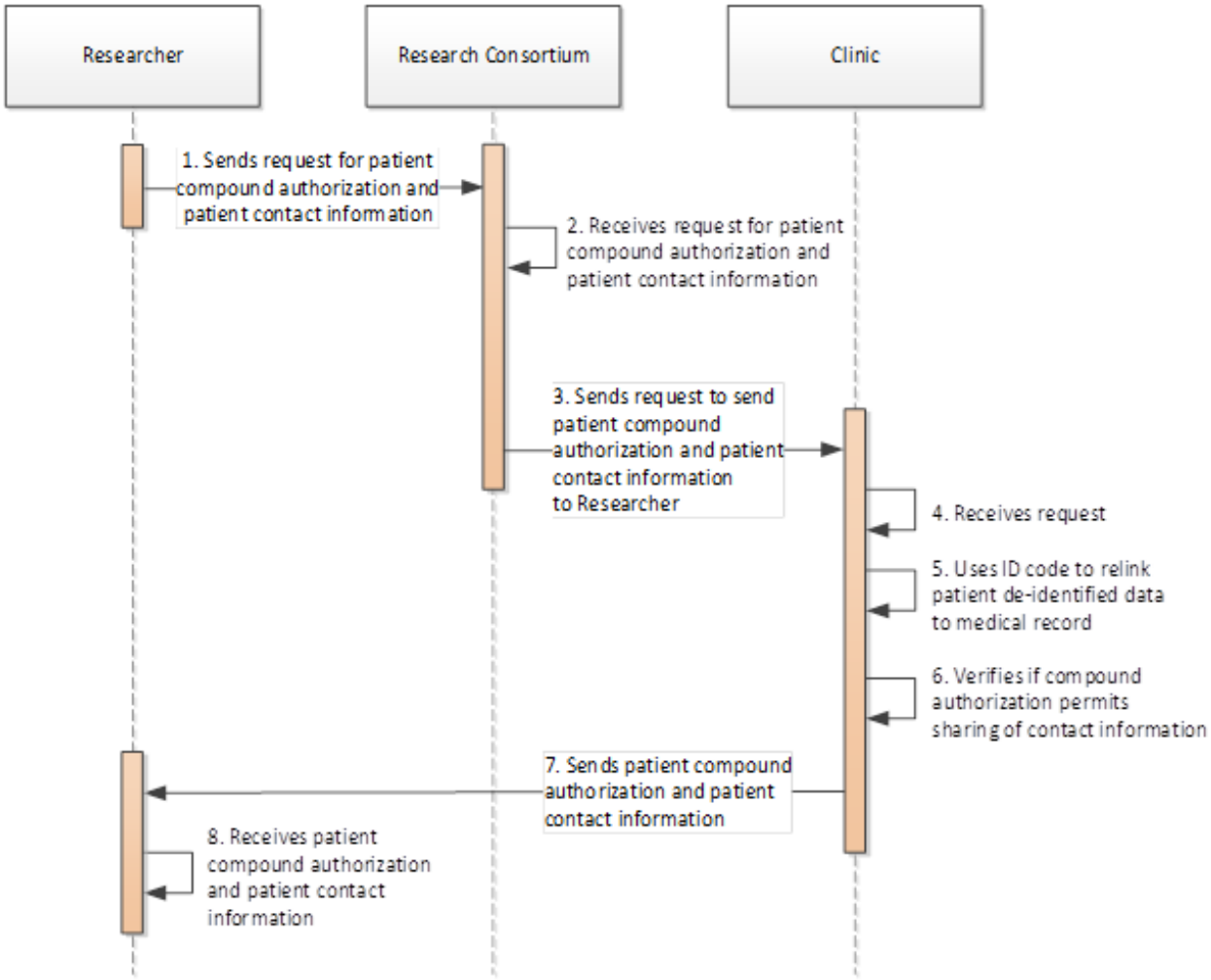


Table 5: Base Flow of Consent Scenario 1 Part 2: An Outside Researcher Contacts Alice Regarding Participation in a New Study

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Researcher	Data Requester	Sends request for patient compound authorization and patient contact information	Request for patient compound authorization and patient contact information	Request for patient compound authorization and patient contact information	Information Interchange
2	Research Consortium	Data Receiver	Receives request for patient compound authorization and patient contact information	Request for patient compound authorization and patient contact information	Request for patient compound authorization and patient contact information	Information Interchange
3	Research Consortium	Data Requester	Sends request to send patient compound authorization and patient contact information to Researcher	Request to send patient compound authorization and patient contact information	Request to send patient compound authorization and patient contact information	Information Interchange
4	Clinic	Data Receiver	Receives request for patient compound authorization and patient contact information	Request to patient compound authorization and patient contact information	Request to send patient compound authorization and patient contact information	Information Interchange
5	Clinic	Data Source	Uses ID code to relink patient de-identified data to medical record	Request to patient compound authorization and patient contact information	Relinked patient de-identified data	System
6	Clinic	Data Source	Verifies if compound authorization permits sharing of contact information	Relinked patient de-identified data	Relinked patient de-identified data	System
7	Clinic	Data Source	Sends patient compound authorization and patient contact information	Relinked patient de-identified data	Relinked patient de-identified data	Information Interchange
8	Researcher	Data Receiver	Receives patient compound authorization and patient contact information	Patient compound authorization and patient contact information	End Flow	Information Interchange

Table 6: System Requirements of Consent Scenario 1 Part 2: An Outside Researcher Contacts Alice Regarding Participation in a New Study

System	System Requirement
Clinic	Uses ID code to relink patient de-identified data to medical record
Clinic	Verifies if compound authorization permits sharing of contact information

6.1.3 Part 3: Alice Revokes Her Consent for Re-Contact

Alice begins to receive several requests for participation in studies that indicate her data was queried from the research consortium. She no longer wishes to receive requests for participation in studies that she does not directly seek out. Alice logs into her patient portal and updates her compound authorization revoking her consent to re-contact. The change in consent directive status updates the consent management system and notifies the clinic, which updates Alice's consent preference. The updated consent metadata indicating her revocation of consent to re-contact is sent to the research consortium. Alice no longer receives requests for participation in future research studies.

Figure 3: Sequence Diagram for Consent Scenario 1 Part 3: Alice Revokes Her Consent for Re-Contact

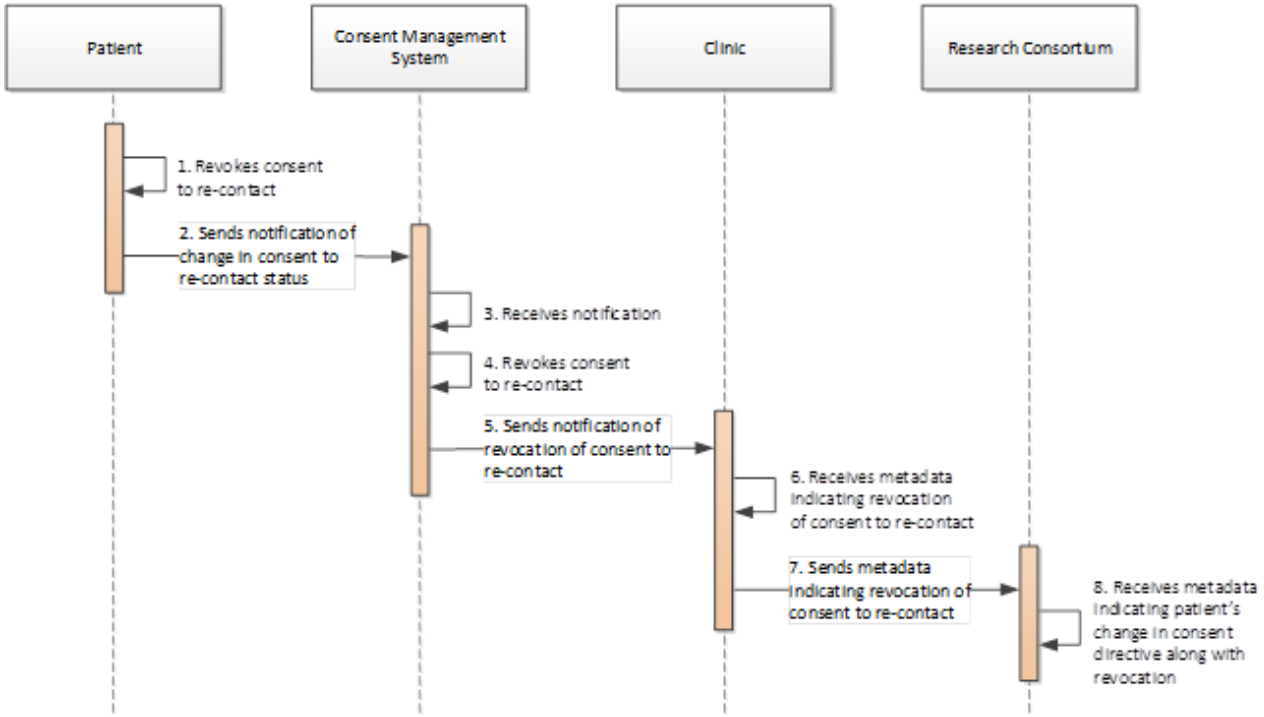


Table 7: Base Flow of Consent Scenario 1 Part 3: Alice Revokes Her Consent for Re-Contact

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Patient	Data Source	Revokes consent to re-contact	Revocation of consent to re-contact	Revocation of consent to re-contact	System
2	Patient	Data Source	Sends notification of change in consent to re-contact status	Revocation of consent to re-contact	Notification of change in consent	Information Interchange
3	Consent Management System	Data Receiver	Receives notification	Notification of change in consent	Notification of change in consent	Information Interchange
4	Consent Management System	Data Source	Revokes consent for re-contact	Notification of change in consent	Revocation of consent to re-contact	System
5	Consent Management System	Data Source	Sends notification of revocation of consent to re-contact	Revocation of consent to re-contact	Notification of change in consent	Information Interchange
6	Clinic	Data Receiver	Receives metadata indicating revocation of consent to re-contact	Notification of change in consent	Metadata indicating revocation of consent to re-contact	Information Interchange
7	Clinic	Data Source	Sends metadata indicating revocation of consent to re-contact	Metadata indicating revocation of consent to re-contact	Metadata indicating revocation of consent to re-contact	Information Interchange
8	Research Consortium	Data Receiver	Receives metadata indicating patient change in consent directive along with revocation	Metadata indicating revocation of consent to re-contact along with revocation	End Flow	Information Interchange

Table 8: System Requirements of Consent Scenario 1 Part 3: Alice Revokes Her Consent for Re-Contact

System	System Requirement
Patient	Revokes consent to re-contact
Consent Management System	Revokes consent to re-contact

6.2 Consent Scenario 2 Minor Genetic Research

Table 10 summarizes the key components in Consent Scenario 2 – Minor Genetic Research. This scenario is split into four parts, all of which illustrate the exchange of consent. This user story showcases the exchange of an assertion of consent. This consent scenario also incorporates the exchange of data provenance and consent of a minor.

This consent scenario begins with Alice participating in a study as a minor. Under the Common Rule, an IRB may determine whether a minor assent is needed for participation in research and how it should be documented. An assent does not negate the need for an informed consent signed by the parent or guardian of the minor.[4] When Alice is no longer considered a minor—a determination made by state law—the biobank re-contacts Alice to obtain her consent as an adult.

Also notable is that part 1 of this consent scenario illustrates the exchange of a Common Rule informed consent and not a compound authorization, which would include a HIPAA patient authorization. This is because the local university in part 1 is not meant to meet the definition of a Covered Entity under HIPAA, thereby falling outside the scope of HIPAA requirements.

This scenario utilizes the same privacy preserving technologies detailed in consent scenario 1.

Table 9: Scenario 2 Key Components

Data exchanged:	Part 1: Assertion of assent / consent (from university to Biobank A); blood biospecimen; PHI Part 2: Assertion of consent (from Biobank A to researcher); blood biospecimen; PHI Part 3: Assertion of consent (from researcher A to PCP); PHI Part 4: HIPAA patient authorization (from research staff B to PCP); PHI
Other notable elements:	Assertion of consent Capture and exchange of provenance data Consent from a minor Use of privacy-preserving technologies Genetic research / use of biospecimens Use of current research study on ClinicalTrials.gov

6.2.1 Part 1: Minor Alice Agrees to Participate in Hemochromatosis Study

A local university is running a study regarding prevalence of hereditary HFE (hemochromatosis). Based on family history and risk factors, Alice, age 17, is interested in genetic testing to determine if she carries mutations in her HFE genes.[5] Alice and her parents go to the university's phlebotomist station for blood withdrawal. Alice signs an informed assent, which is required by the university's IRB; Alice's parents sign an informed consent on her behalf that also states Alice's biospecimen can be stored and she may be re-contacted for its further use and/or participation in future studies.[6]

4 45 CFR 46.408

5 "Hereditary hemochromatosis (HH) is a genetic disease that alters the body's ability to regulate iron absorption. If correctly diagnosed, HH is easily and effectively treated, but if untreated, it can lead to severe organ damage. Caucasians of northern European descent are at highest risk. An estimated one million people in the United States have hereditary hemochromatosis." From: https://www.genome.gov/Genetic-Disorders/Hereditary-Hemochromatosis

6 Per 45 CFR 46.408 (the Common Rule), an IRB may determine whether a minor assent is needed for participation in research and how it should be documented. An assent does not negate the need for an informed consent signed by a parent or guardian of the minor.

Alice's assent and the consent signed on her behalf by her parents are stored at the local university. Alice's blood biospecimen is sent to Biobank A along with two assertions—one for assent and one for consent—as directed in the agreement governing the exchange of consent between organizations.[7]

Figure 4: Sequence Diagram of Consent Scenario 2 Part 1: Minor Alice Agrees to Participate in Hemochromatosis Study

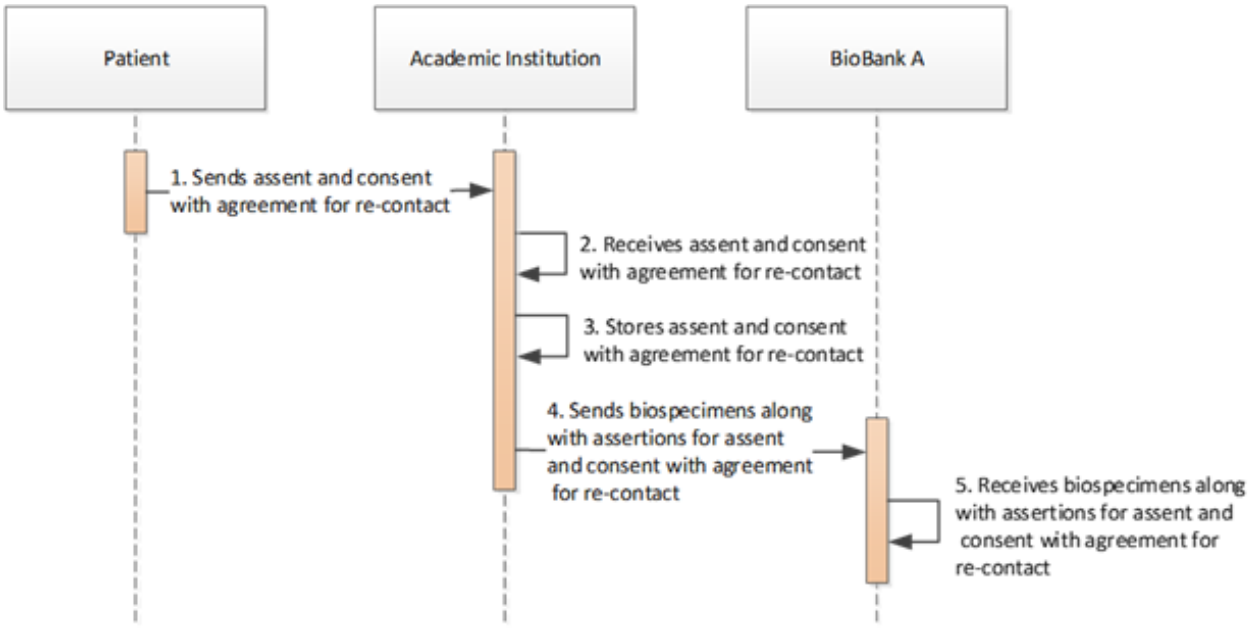


Table 10: Base Flow of Consent Scenario 2 Part 1: Minor Alice Agrees to Participate in Hemochromatosis Study

Step #	Actor	Role	Event/ Description	Inputs	Outputs	Type of Requirement
1	Patient	Data Source	Sends assent and consent for re-contact	Assent and consent for re-contact	Assent and consent for re-contact	Information Interchange
2	Academic Institution	Data Receiver	Receives assent and consent for re-contact	Assent and consent for re-contact	Assent and consent for re-contact	Information Interchange
3	Academic Institution	Data Source	Stores assent and consent for re-contact	Assent and consent for re-contact	Assent and consent for re-contact	System
4	Academic Institution	Data Source	Sends biospecimens along with assertions for assent and consent for re-contact	Assent and consent for re-contact	Biospecimens along with assertions	Information Interchange
5	Biobank A	Data Receiver	Receives biospecimens along with assertions for assent and consent for re-contact	Biospecimens along with assertions	End Flow	Information Interchange

[7] In practice, when an assertion is used, it is generally done pursuant to an overarching arrangement (memorandum of understanding, contract, rules of engagement) between organizations where the burden of proof of consent is on the asserting organization. Contracts generally mandate that the asserting organization sends the consent, retains the consent indefinitely, or produces the consent when needed by another organization in a timely manner.

Table 11: System Requirements of Consent Scenario 2 Part 1: Minor Alice Agrees to Participate in Hemochromatosis Study

System	System Requirement
Academic Institution	Stores assent and consent for re-contact

6.2.2 Part 2: Alice Re-Consents and Provides Her Biospecimen For Further Research

One year later, upon recognizing that Alice's current consent needs updating due to her reaching age of consent, Biobank A contacts the local university to obtain Alice's informed consent as an adult. The local university contacts Alice and requests that she submit an electronic consent for the storage of her biospecimen and consent for re-contact; Alice provides consent. The local university stores the consent and sends the assertion to Biobank A.

Shortly after, a researcher visits the National Cancer Institute's Specimen Resource Locator for blood biospecimens for a hematological study for which IRB approval has already been granted. The resource locator identifies four biobanks that maintain the biospecimens needed for research. The researcher follows each biobank's protocol to request and receive blood biospecimens, including Biobank A's protocol. Biobank A approves the request. Biobank A queries its repository. Biobank A sends an assertion to the researcher indicating that Alice's consent is on file and forwards Alice's contact information. The researcher contacts Alice and she consents to the use of her biospecimen in the study.

Figure 5: Sequence Diagram of Consent Scenario 2 Part 2: Alice Re-Consents and Provides Her Biospecimen for Further Research

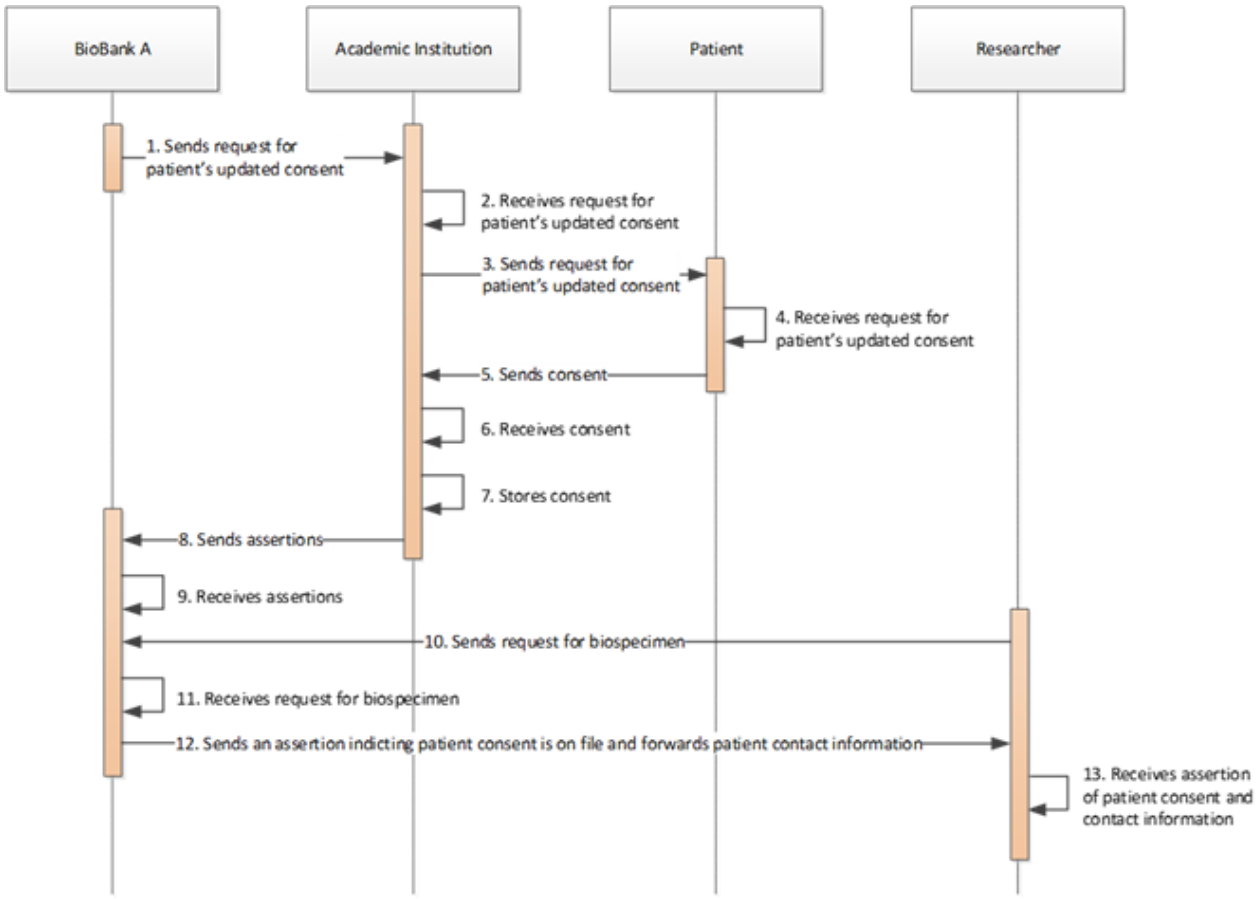


Table 12: Base Flow of Consent Scenario 2 Part 2: Alice Re-Consents and Provides Her Biospecimen for Further Research

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Biobank A	Data Requester	Sends request for patient's updated consent	Request for patient's updated consent	Request for patient's updated consent	Information Interchange
2	Academic Institution	Data Receiver	Receives request for patient's updated consent	Request for patient's updated consent	Request for patient's updated consent	Information Interchange
3	Academic Institution	Data Source	Sends request for consent of biospecimen storage and consent for re-contact	Request for patient's updated consent	Request for consent of biospecimen storage and consent for re-contact	Information Interchange

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
4	Patient	Data Receiver	Receives request for consent of biospecimen storage and consent for re-consent	Request for consent of biospecimen storage and consent for re-contact	Request for consent of biospecimen storage and consent for re-contact	Information Interchange
5	Patient	Data Source	Sends consent	Sent Consent	Sent Consent	Information Interchange
6	Academic Institution	Data Receiver	Receives consent	Sent Consent	Sent Consent	Information Interchange
7	Academic Institution	Data Source	Stores consent	Sent Consent	Stored Consent	System
8	Academic Institution	Data Source	Sends assertions	Stored Consent	Assertions	Information Interchange
9	Biobank A	Data Receiver	Receives assertions	Assertions	End Flow	Information Interchange
10	Researcher	Data Requester	Sends request for biospecimen	Request for biospecimen	Request for biospecimen	Information Interchange
11	Biobank A	Data Receiver	Receives request for biospecimen	Request for biospecimen	Request for biospecimen	Information Interchange
12	Biobank A	Data Source	Sends an assertion indicating patient consent is on file and forwards patient contact information	Request for biospecimen	Assertion of patient consent and contact information	Information Interchange
13	Researcher	Data Receiver	Receives assertion of patient consent and contact information	Assertion of patient consent and contact information	End Flow	Information Interchange

Table 13: System Requirements of Consent Scenario 2 Part 2: Alice Re-Consents and Provides Her Biospecimen for Further Research

System	System Requirement
Academic Institution	Stores consent

6.2.3 Part 3: Researcher Sends Information to Alice's Primary Care Physician (PCP)

During the course of running tests on Alice's biospecimen, the researcher discovers that Alice has a gene mutation that can cause juvenile hemochromatosis. The researcher wants to alert Alice so that she has the opportunity to receive follow-up testing from her PCP.

The researcher contacts Alice and asks if they should forward the new information to a PCP of her choice for follow-up, if necessary. Alice agrees and provides the contact information of her PCP. The researcher transfers the new information with relevant provenance data generated during the study, and assertion of current consent to Alice's PCP.[8] Alice's PCP reviews the information and provenance and contacts Alice for a follow-up visit.

Figure 6: Sequence Diagram of Consent Scenario 2 Part 3: Researcher Sends Information to Alice's PCP for Follow Up

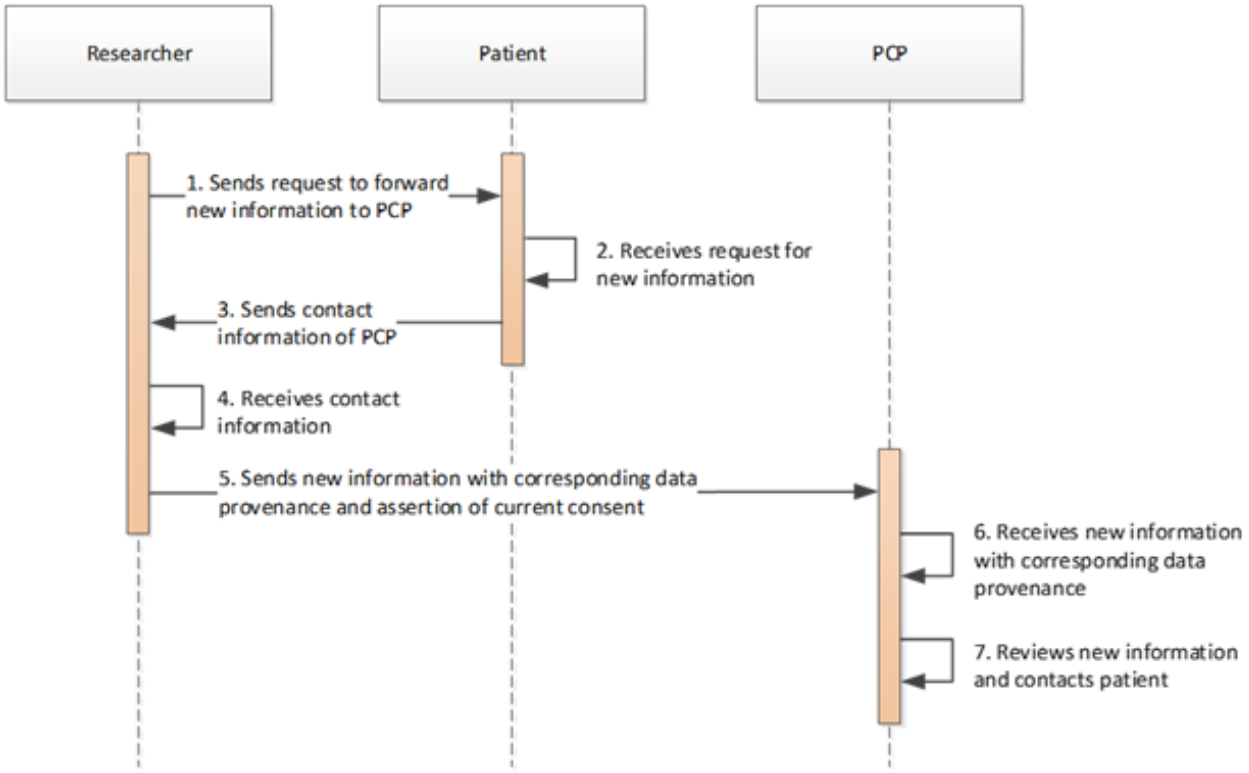


Table 14: Base Flow of Consent Scenario 2 Part 3: Researcher Sends Information to Alice's PCP for Follow Up

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Researcher	Data Requester	Sends request to forward new information to PCP	Request for new information	Request for new information	Information Interchange
2	Patient	Data Receiver	Receives request for new information	Request for new information	Request for new information	Information Interchange

[8] Types of provenance information should include the (1) circumstances for initial collection and storage of biospecimen and subsequent disclosure from Biobank A to researcher, information enabling identification and contacts including the hematologic research study project identifier, sponsors, principle investigator, and applicable regulations governing specimen collection; (2) sources and retrieval location of information about biospecimen analysis; any transformations the research information underwent [e.g., aggregated, disaggregated, de-identified/re-identified—i.e., transforms that could alter the semantics of the data]; copies of research consent directives or locations from which they can be retrieved; and (4) other information that would be helpful for the patient's chosen practitioner to orient themselves to the information they are receiving in order to provide care or help patients enroll in pertinent clinical trials.

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
3	Patient	Data Source	Sends contact information of PCP	Request for new information	Contact information of PCP	Information Interchange
4	Researcher	Data Receiver	Receives contact information	Contact information of PCP	Contact information of PCP	Information Interchange
5	Researcher	Data Source	Sends new information with corresponding data provenance and assertion of current consent	Contact information of PCP	New information with corresponding data provenance and assertion	Information Interchange
6	PCP	Data Receiver	Receives new information with corresponding data provenance	New information with corresponding data provenance and assertion	New information with corresponding data provenance and assertion	Information Interchange
7	PCP	Data Source	Reviews new information and contacts patient	New information with corresponding data provenance and assertion	End Flow	System

Table 15: System Requirements of Consent Scenario 2 Part 3: Researcher Sends Information to Alice's PCP for Follow Up

System	System Requirement
PCP	Reviews new information and contacts patient

6.2.4 Part 4: Alice Joins A Study Involving an FDA Informed Consent and Her PCP Releases Her Medical Records

Alice visits her PCP who tells her that ClinicalTrials.gov has an magnetic resonance imaging (MRI) device trial seeking FDA approval that is looking for candidates such as Alice to investigate whether the device's capabilities will assist providers in determining the extent to which iron overload may have impacted Alice's health. Alice decides to participate in the trial and contacts the research study staff regarding participation. As directed by staff, she submits an electronic Food and Drug Administration (FDA) informed consent and a HIPAA patient authorization for the release of medical records held by her PCP. The research staff sends the HIPAA patient authorization to Alice's PCP who issues Alice's medical records along with provenance of the original research study.

Figure 7: Sequence Diagram of Consent Scenario 2 Part 4: Alice Joins a Study Involving an FDA Informed Consent and Her PCP Releases Her Medical Records

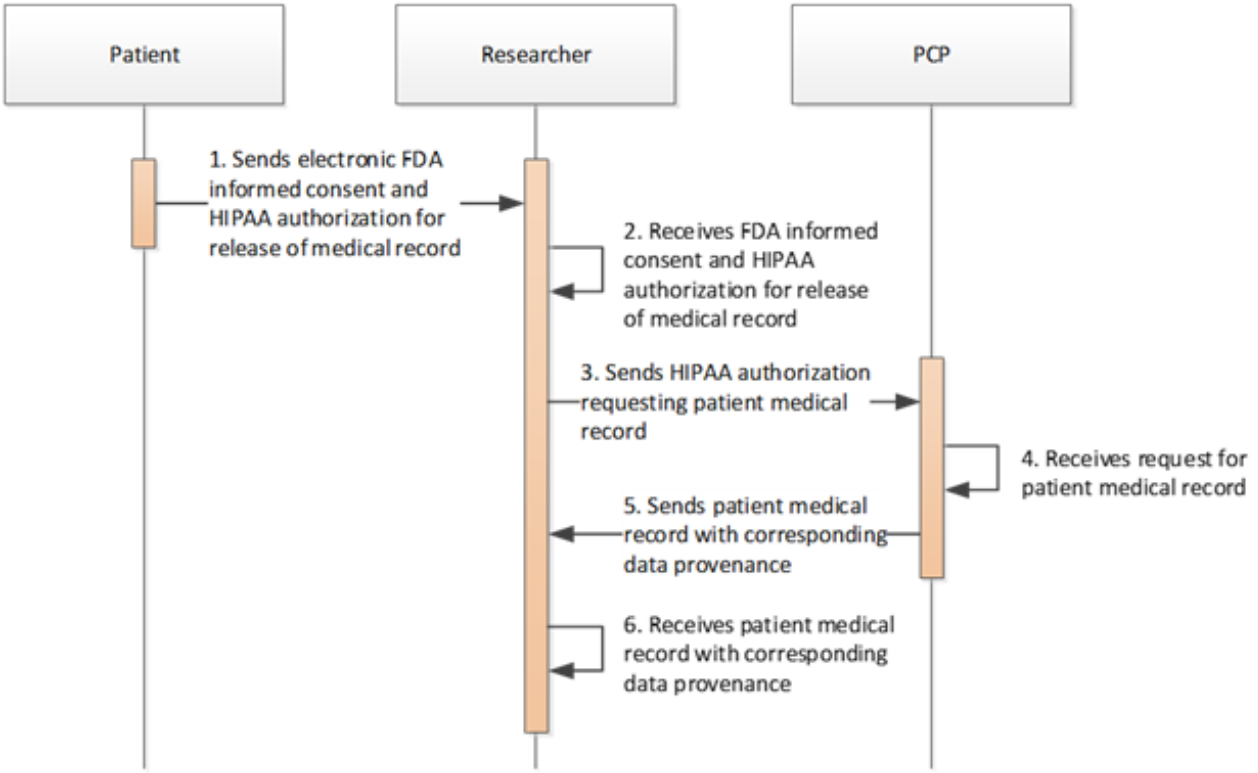


Table 16: Base Flow of Consent Scenario 2 Part 4: Alice Joins a Study Involving an FDA Informed Consent and Her PCP Releases Her Medical Records

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Patient	Data Source	Sends electronic FDA informed consent and HIPAA authorization for release of medical record	Electronic FDA informed consent and HIPAA authorization	Electronic FDA informed consent and HIPAA authorization	Information Interchange
2	Researcher	Data Receiver	Receives FDA informed consent and HIPAA authorization for release of medical record	Electronic FDA informed consent and HIPAA authorization	Electronic FDA informed consent and HIPAA authorization	Information Interchange
3	Researcher	Data Requester	Sends HIPAA authorization requesting patient medical record	Electronic FDA informed consent and HIPAA authorization	HIPAA authorization requesting patient medical record	Information Interchange

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
4	PCP	Data Receiver	Receives request for patient medical record	HIPAA authorization requesting patient medical record	HIPAA authorization requesting patient medical record	Information Interchange
5	PCP	Data Source	Sends patient medical record with corresponding data provenance	HIPAA authorization requesting patient medical record	Patient medical record with corresponding data provenance	Information Interchange
6	Researcher	Data Receiver	Receives patient medical record with corresponding data provenance	Patient medical record with corresponding data provenance	End flow	Information Interchange

Table 17: System Requirements of Consent Scenario 2 Part 4: Alice Joins a Study Involving an FDA Informed Consent and Her PCP Releases Her Medical Records

System	System Requirement
Researcher	Stores FDA informed consent and HIPAA authorization

6.3 Consent Scenario 3 Mobile App Study

Table 19 summarizes the key components represented in Consent Scenario 3 – Mobile App Study. Similar to the other scenarios, this scenario utilizes privacy-preserving technologies that are detailed in Consent Scenario 1 – Participation in Research Study with Revocation of Consent.

In Part 4 of this Scenario, Alice signs a broad consent for secondary research use of her PHI[9]. The type of broad consent used in this story is described further in the updated Common Rule published in January 2017 at 45 CFR 46.116(d). The user story also is intended to align with *All of Us* Research Program aspects of large-scale cohort research and use of HIPAA Patient Right of Access to donate data for research.

[9] The HIPAA Privacy Rule establishes a set of national standards for the use and disclosure of individually identifiable health information—often called protected health information (PHI)—by covered entities, as well as standards for providing individuals' with health information privacy rights and helping individuals understand and control how their health information is used.

Table 18: Consent Scenario 3 Key Components

Data Exchanges	Part 1: PHI Part 2: Electronic consent (from research organization to academic institution); contact information Part 3: HIPAA patient authorization (from academic institution to PCP; from academic institution to HIE); PHI Part 4 (Alternate): Broad consent (from academic institution to large-scale cohort research program; PHI
Other notable elements:	Mobile-app study (involves non-Covered Entity under HIPAA) Includes self-reported PGHD Capture and exchange of provenance data Broad consent in Part 4 Uses privacy-preserving technologies

6.3.1 Part 1: Alice Joins a Study on Her Mobile App

Alice's father has Parkinson's Disease and tells Alice about an observational study sponsored by a nonprofit research organization his doctor had recommended for his family and friends. The study is run from a mobile app, and involves downloading the mobile app, providing consent, inputting certain health data, including periodic self-reported patient-generated health data, and allowing certain health indicators (such as balance and gait) to be tracked via phone sensors. Alice downloads the app. As part of the consent process, Alice is asked if she would like to be re-contacted for participation in other similar studies for which she may qualify. She checks a box indicating her consent to be re-contacted. She also checks a box in the mobile app indicating her consent to participate in the study and consent for release of contact information to interested researchers. The non-profit research organization records Alice's consent directive. Alice's data along with provenance of the data input is collected in a repository.

Figure 8: Sequence Diagram of Consent Scenario 3 Part 1: Alice Joins a Study on Her Mobile App

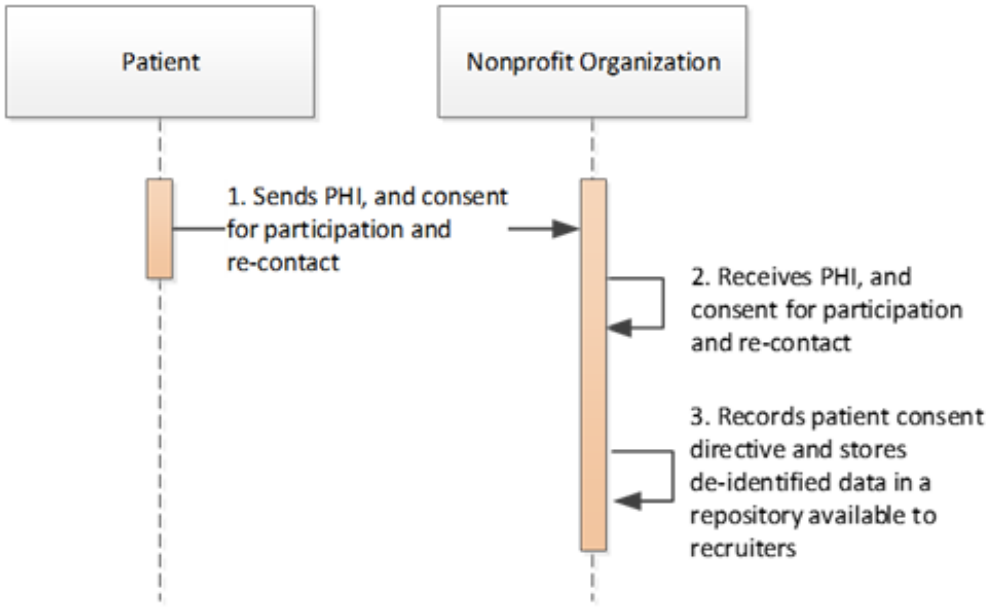


Table 20: Base Flow of Consent Scenario 3 Part 1: Alice Joins a Study on Her Mobile App

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Patient	Data Source	Sends PHI, and consent for participation and re-contact	PHI and consent for participation and re-contact	PHI and consent for participation and re-contact	Information Interchange
2	Nonprofit Organization	Data Receiver	Receives PHI, and consent for participation and re-contact	PHI and consent for participation and re-contact	PHI and consent for participation and re-contact	Information Interchange
3	Nonprofit Organization	Data Source	Records patient consent directive and stores de-identified data in a repository available to recruiters	PHI and consent for participation and re-contact	End Flow	System

Table 19: System Requirements of Consent Scenario 3 Part 1: Alice Joins a Study on Her Mobile App

System	System Requirement
Nonprofit Organization	Records patient consent directive and stores de-identified data in a repository available to recruiters

6.3.2 Part 2: An Academic Institution is Interested in Obtaining Data from the Mobile App

An academic institution participating in a large-scale cohort research program and conducting an IRB-approved research study on Parkinson's Disease reaches out to the nonprofit research organization to see whether they may have participants that would be appropriate for their research study. The nonprofit research organization discusses the purpose of their organization, the type of data they collect, and the current number of participants in their project. The academic institution would like to broaden the type of data they collect and seek further IRB approval. The IRB approves contacting participants of the mobile app study conditioned upon the receipt of the patients' original consent for re-contact. The academic institution requests Alice's consent from the nonprofit research organization. The nonprofit research organization sends a copy of Alice's consent to the academic institution and Alice's contact information.

Figure 9: Sequence Diagram of Consent Scenario 3 Part 2: An Academic Institution Is Interested in Obtaining Data from the Mobile App

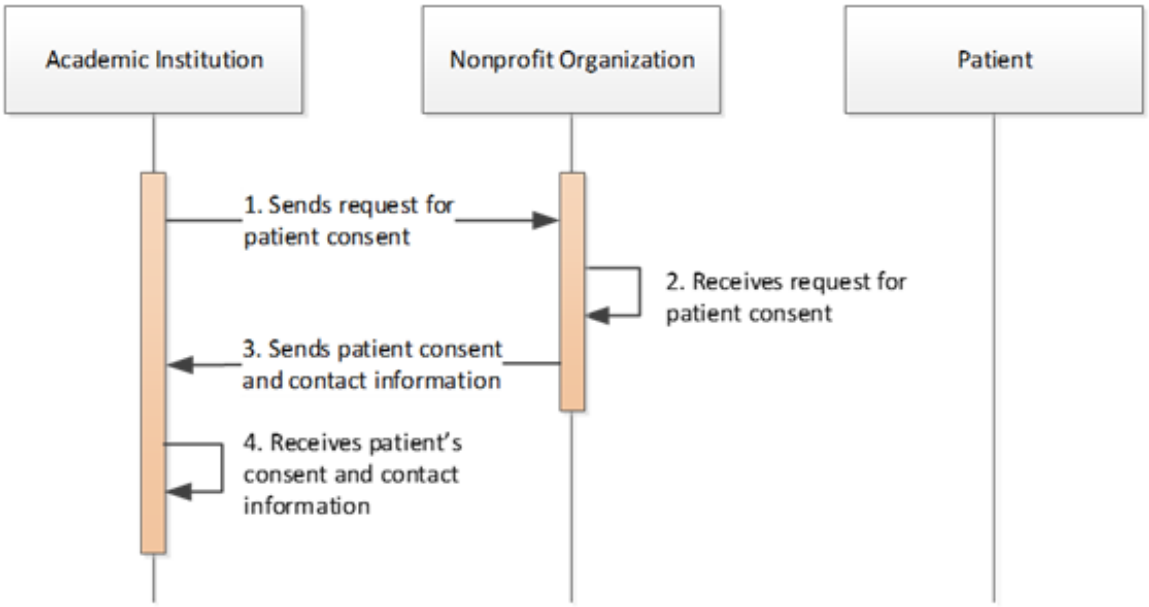


Table 20: Base Flow of Consent Scenario 3 Part 2: An Academic Institution Is Interested in Obtaining Data from the Mobile App

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Academic Institution	Data Requester	Sends request for patient consent	Request for patient consent	Request for patient consent	Information Interchange
2	Nonprofit Organization	Data Receiver	Receives request for patient consent	Request for patient consent	Request for patient consent	Information Interchange
3	Nonprofit Organization	Data Source	Sends patient consent and contact information	Request for patient consent	Patient consent and contact information	Information Interchange
4	Academic Institution	Data Receiver	Receives patient's consent and contact information	Patient consent and contact information	End Flow	Information Interchange

Table 21: System Requirements of Consent Scenario 3 Part 2: An Academic Institution Is Interested in Obtaining Data from the Mobile App

System	System Requirement
N/A	N/A

6.3.3 Part 3: Alice Participates in The Study and The Academic Institution Amasses Alice's Medical Records

The academic institution contacts Alice and explains their research study. As part of the study, the academic institution would like to retrieve provenance information and data collected pursuant to the mobile app study, health data from her PCP, and any data collected in the state HIE. In order for her to participate in this study, she will need to provide consent for participation and authorization for the release of her records, where appropriate. The academic institution collects Alice's informed consent and HIPAA patient authorization separately. It sends her HIPAA patient authorization to her PCP and state HIE for the release of her medical records and information showing the provenance of the data released.

Figure 10: Sequence Diagram of Consent Scenario 3 Part 3: Alice Participates in The Study and the Academic Institution Amasses Alice's Medical Records

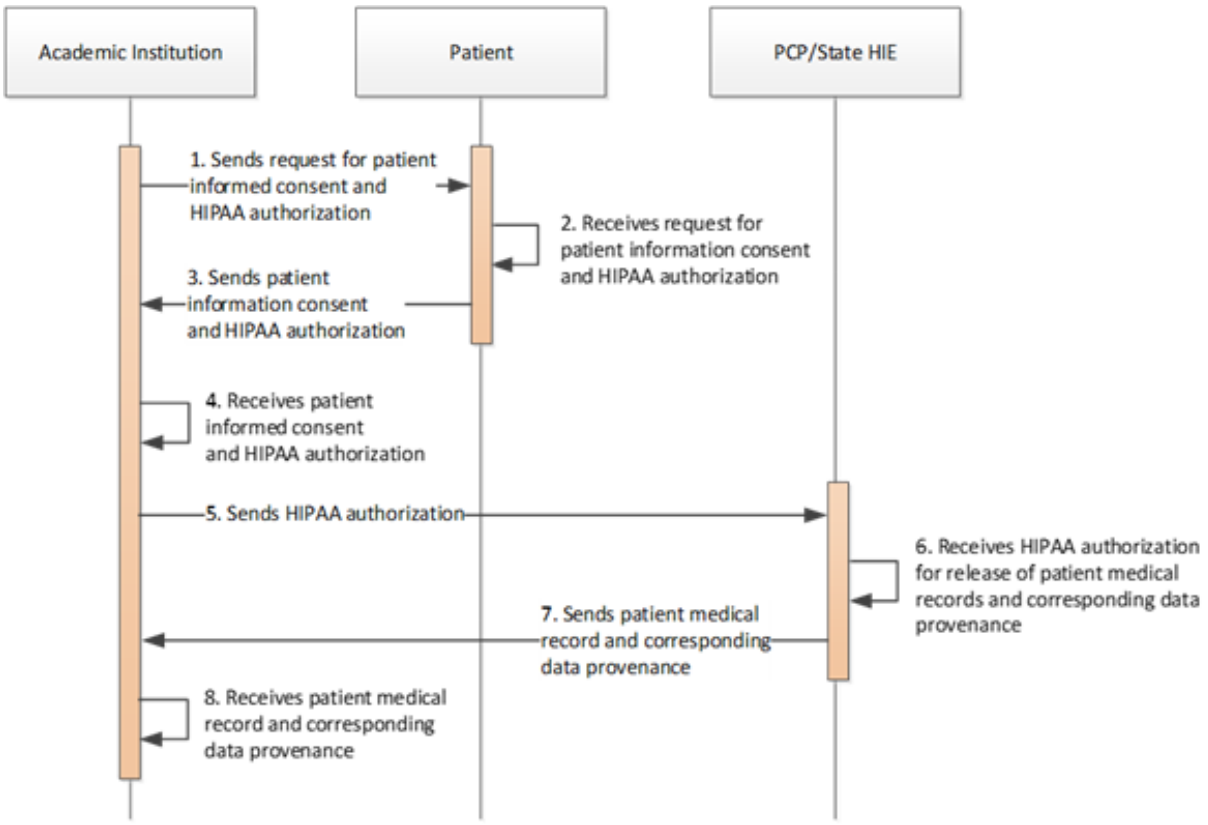


Table 22: Base Flow of Consent Scenario 3 Part 3: Alice Participates in The Study and the Academic Institution Amasses Alice's Medical Records

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Academic Institution	Data Requester	Sends request for patient informed consent and HIPAA authorization	Request for patient informed consent and	Request for patient informed consent and	Information Interchange

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
				HIPAA authorization	HIPAA authorization	
2	Patient	Data Receiver	Receives request for patient informed consent and HIPAA authorization	Request for patient informed consent and HIPAA authorization	Request for patient informed consent and HIPAA authorization	Information Interchange
3	Patient	Data Source	Sends patient informed consent and HIPAA authorization	Request for patient informed consent and HIPAA authorization	Patient informed consent and HIPAA authorization	Information Interchange
4	Academic Institution	Data Receiver	Receives patient informed consent and HIPAA authorization	Patient informed consent and HIPAA authorization	Patient informed consent and HIPAA authorization	Information Interchange
5	Academic Institution	Data Source	Sends HIPAA authorization	Patient informed consent and HIPAA authorization	HIPAA authorization	Information Interchange
6	PCP/State HIE	Data Receiver	Receives HIPAA authorization for release of patient medical records and corresponding data provenance	HIPAA authorization	HIPAA authorization	Information Interchange
7	PCP/State HIE	Data Source	Sends patient medical record and corresponding data provenance	HIPAA authorization	Patient medical record and corresponding data provenance	Information Interchange
8	Academic Institution	Data Receiver	Receives patient medical record and corresponding data provenance	Patient medical record and corresponding data provenance	End Flow	Information Interchange

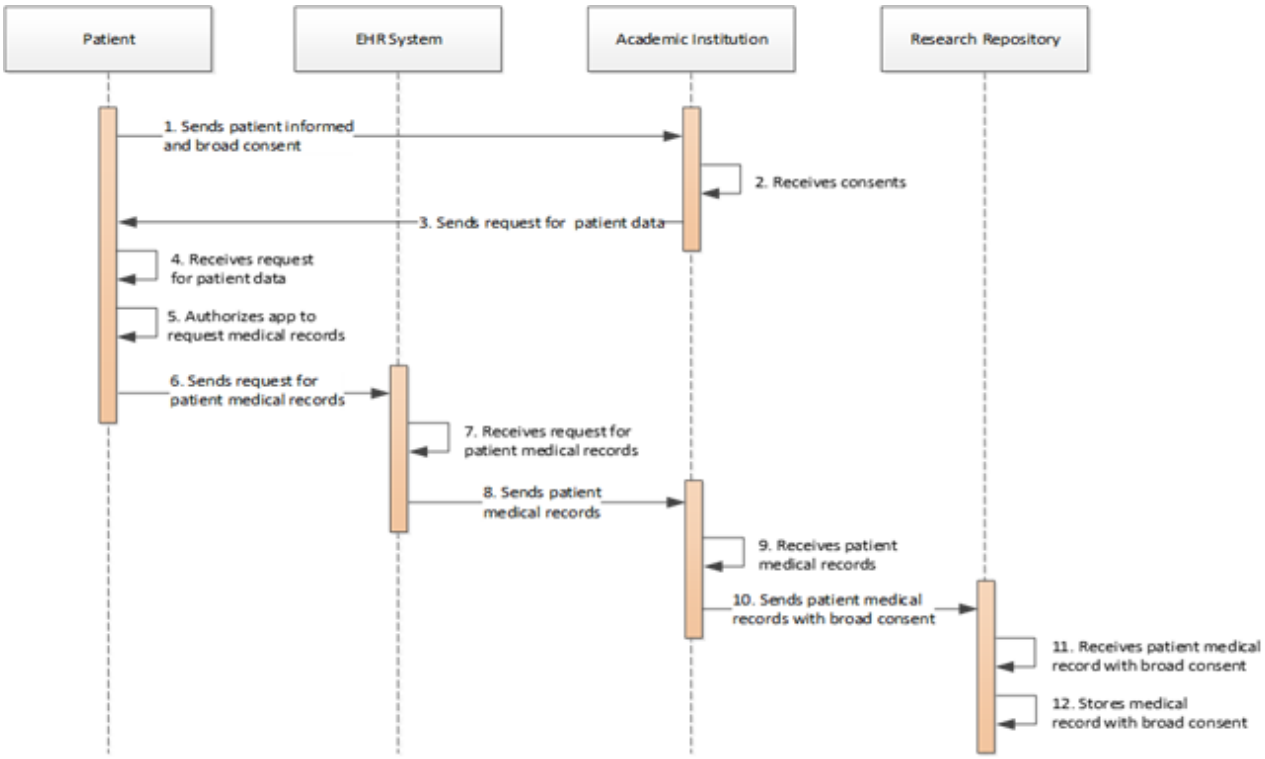
Table 23: System Requirements of Consent Scenario 3 Part 3: Alice Participates in The Study and the Academic Institution Amasses Alice's Medical Records

System	System Requirement
N/A	N/A

6.3.4 Part 4 (Alternate): Alice Donates Her Data and Provides Broad Consent for Unspecified Future Research

The academic institution contacts Alice and explains their research study. Alice decides to participate and also provides broad consent for secondary research using her PHI. As part of the study, the academic institution requests Alice to directly donate her data from her PCP and other providers through the mobile app using her patient right of access under HIPAA.[10] Through the mobile app, Alice selects the specific EHR her provider(s) use. She is then directed to enter the credentials given to her by her provider(s). She allows the app access and the app is provided with an authorization token to use to query her records. Alice selects components from her common clinical dataset to share with the academic institution. The academic institution sends Alice's data and broad consent to the repository held by the large-scale cohort research program.

Figure 11: Sequence Diagram of Consent Scenario 3 Part 4: Alice Donates Her Data and Provides Broad Consent for Unspecified Future Research



[10] See 45 CFR 164.524

Table 24: Base Flow of Consent Scenario 3 Part 4: Alice Donates Her Data and Provides Broad Consent for Unspecified Future Research

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Patient	Data Source	Sends patient informed and broad consent	Patient informed and broad consent	Patient informed and broad consent	Information Interchange
2	Academic Institution	Data Receiver	Receives consent	Patient informed and broad consent	Patient informed and broad consent	Information Interchange
3	Academic Institution	Data Requester	Sends request for patient data	Patient informed and broad consent	Request for patient data	Information Interchange
4	Patient	Data Receiver	Receives request for patient data	Request for patient data	Request for patient data	Information Interchange
5	Patient	Data Receiver	Authorizes app to request patient medical records	Request for patient data	App authorized to request medical records	System
6	Patient	Data Requester	Sends request for patient medical record	App authorized to request medical records	Request for patient medical records	Information Interchange
7	EHR System	Data Receiver	Receives request for medical records	Request for patient medical records	Request for patient medical records	Information Interchange
8	EHR System	Data Source	Sends patient medical records	Request for patient medical records	Patient medical records	Information Interchange
9	Academic Institution	Data Receiver	Receives patient medical records	Patient medical records	Patient medical records with broad consent	Information Interchange
10	Academic Institution	Data Source	Sends patient medical records	Patient medical records with broad consent	Patient medical records with broad consent	Information Interchange
11	Research Repository	Data Receiver	Receives patient medical record	Patient medical record with broad consent	Patient medical record with broad consent	Information Interchange
12	Research Repository	Data Source	Stores medical record with broad consent	Patient medical record with broad consent	End Flow	System

Table 25: System Requirements of Consent Scenario 3 Part 4: Alice Donates Her Data and Provides Broad Consent for Unspecified Future Research

System	System Requirement
Patient	Authorizes app to request patient medical records
Research Repository	Stores medical record with broad consent

6.4 Consent Scenario 4 Translational Research

This consent scenario explores the use of a patient portal that enables Alice to track her Patient Right of Access, informed consent directives, update or revoke them, and to receive consent receipts as provenance tracking for the use of her data for research.

Additionally, secondary research flows described in this scenario explore the use of interoperable application program interfaces (API) to enable increased data liquidity between translational research and other types of research to form a virtual feedback loop. Alice sustains poly-traumatic injuries following an improvised explosive device (IED) exposure during a recent tour of duty.[11] She's been taking an antioxidant to lower risk of ocular blast trauma. She is now being cared for by a Veterans Affairs (VA) ophthalmologist who is coordinating her care for chronic pain with her Community Pain Management Specialist (covered by 42 CFR Part 2) because of her history of SUD. Both of her providers recommend that she join the concurrent VA Ocular Blast Trauma (OBT) and Opiate Pain Management (OPM) Translational Clinical Trials (TCT). As part of the clinical trial, her VA ophthalmologist regularly sends her de-identified optical coherence tomography retinal scans as input to Google's Deep Mind, a super computer capable of machine learning to monitor any degradation of her ocular health. Alice's Community Pain Management Specialist sends her de-identified opiate pain management information to the same supercomputer to monitor her susceptibility to opiate addiction.

Table 26: Consent Scenario 4 Key Components

Data Exchanges	VA Form 10-0493 Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research Patient Right of Access Consent Directive VA Form 10-1086 Informed Consent Provenance Registration of OBT/OPM Clinical Trial Data and Biospecimen with NIH Data and Bio repositories Re-contacting for potentially clinically actionable findings and for participation in potentially beneficial clinical trials tuned to secondary research findings Global Rare Disease Registry model registry of CDEs for entry of patient data into any rare disease registry NIH Standard Data Use Limitation as encoded by the Global Alliance for Genomic Health [GA4GH] Consent Codes[12]
Other Notable Elements	Translational Research Patient Right of Access Precision Medicine Re-contacting: Points to Consider for Institutions and Institutional Review Boards in Submission and Secondary Use of Human Genomic Data under the National Institutes of Health Genomic Data Sharing Policy Registration of Research Findings and Specimens in NIH Data Repositories and Biorepositories[13] Use of Machine Learning Systems such as Google DeepMind

[11] Ocular trauma is the fourth most common injury sustained in military combat today. https://en.wikipedia.org/wiki/Blast-related_ocular_trauma

[12] Dyke SO, Philippakis AA, Rambla De Argila J, et al. Consent Codes: Upholding Standard Data Use Conditions. PLoS Genet. 2016;12(1):e1005772. Published 2016 Jan 21. doi:10.1371/journal.pgen.1005772

[13] In order to comply with NIH Genomic Data Sharing Policy for Human and Non-Human Data: Guidance for Institutions Submitting Grant Applications and Contract Proposals the OBT Clinical Trial submits a NIH Extramural Institutional Certification, which lists the Data Use Limitations offered to OBT research participants in accordance with the National Institutes of Health Points to Consider in Developing Effective Data Use Limitation Statements.

	Secondary Research automated access control based on ability to comply with Data Use Limitations derived from Informed Consents when registering clinical trial data and specimen into NIH data and bio repositories.

6.4.1 Part 1: Alice Meets Recruitment Counselor for Enrollment

To participate in the OBT/OPM Clinical Trial and to share information for secondary research, Alice is presented with a questionnaire that guides her through the VA FORM 10-1086 Research Informed Consent in patient friendly terms. Alice reviews and signs the OBT/OPM informed consent directive using a tablet.

Her Recruitment Counselor helps her set up her patient portal to enable the continuous flow of designated information about her recent service-related injury to the OBT/OPM clinical trial.

Alice discusses her consent options with her Recruitment Counselor. If Alice signs the VA Form 10-0493 Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research, her entire medical record would be disclosed to the Clinical Trial. Instead they choose to exercise Alice's Patient Right of Access (PRA) under HIPAA and 42 CFR Part 2. Alice makes two PRA consent directives authorizing the VA Ophthalmologist and the Community Pain Management Specialist to disclose only the information about her recent service related injury to the OBT/OPM clinical trials. She digitally signs the PRA consent directives.

Figure 12: Sequence Diagram of Consent Scenario 4 Part 1: Alice Meets Recruitment Counselor for Enrollment

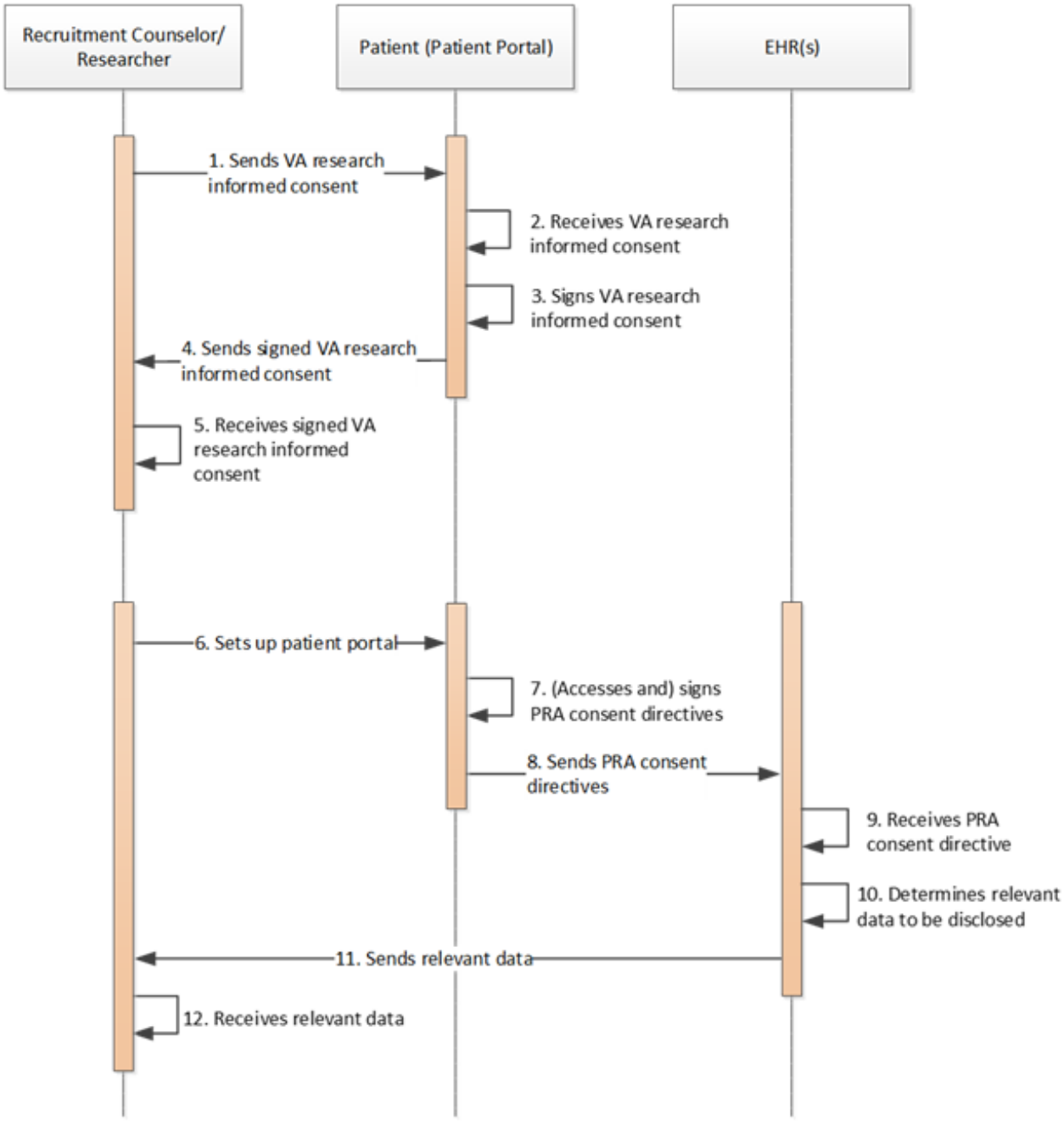


Table 27: Base Flow of Consent Scenario 4 Part 1: Alice Meets Recruitment Counselor for Enrollment

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Recruitment Counselor	Data Source	Sends VA research informed consent	VA research informed consent	VA research informed consent	Information Interchange
2	Patient (Patient Portal)	Data Receiver	Receives VA research informed consent	VA research informed consent	VA research informed consent	Information Interchange
3	Patient (Patient Portal)	Data Source	Signs VA research informed consent	VA research informed consent	Signed VA research informed consent	System
4	Patient (Patient Portal)	Data Source	Sends signed VA research informed consent	Signed VA research informed consent	Signed VA research informed consent	Information Interchange
5	Recruitment Counselor	Data Receiver	Receives signed VA research informed consent	Signed VA research informed consent	Signed VA research informed consent	Information Interchange
6	Recruitment Counselor	Data Source	Sets up patient portal	Signed VA research informed consent	Established patient portal	System
7	Patient (Patient Portal)	Data Source	Accesses and signs PRA consent directives	Established patient portal	Signed PRA consent directives	System
8	Patient (Patient Portal)	Data Source	Sends PRA consent directives	Signed PRA consent directives	Signed PRA consent directives	Information Interchange
9	EHR(s)	Data Receiver	Receives PRA consent directive	Signed PRA consent directives	Signed PRA consent directives	Information Interchange
10	EHR(s)	Data Source	Determines relevant data to be disclosed	Signed PRA consent directives	Relevant data	System
11	EHR(s)	Data Source	Sends relevant data	Relevant data	Relevant data	Information Interchange
12	Recruitment Counselor	Data Receiver	Receives relevant data	Relevant data	End Flow	Information Interchange

Table 28: System Requirements of Consent Scenario 4 Part 1: Alice Meets Recruitment Counselor for Enrollment

System	System Requirement
Patient (Patient Portal)	Signs VA research informed consent
Recruitment Counselor	Sets up patient portal
Patient (Patient Portal)	Accesses and signs PRA consent directives
EHR(s)	Determines relevant data to be disclosed

6.4.2 Part 2: Clinical Trial Sends Information to Repositories

Alice agreed to donate her de-identified OBT/ OPM trial information to National Institutes of Health (NIH) Repositories and Clinical Trial Repositories and her specimens for secondary research purposes limited to ocular and opiate management research using the option provided by her PRA and the OBT/OPM informed consent directives.

The clinical trial sets up automated transfer of information and biospecimens to the NIH Repositories and Clinical Trial Repositories along with the informed consent metadata.

Figure 13: Sequence Diagram of Consent Scenario 4 Part 2: Clinical Trial Sends Information to Repositories

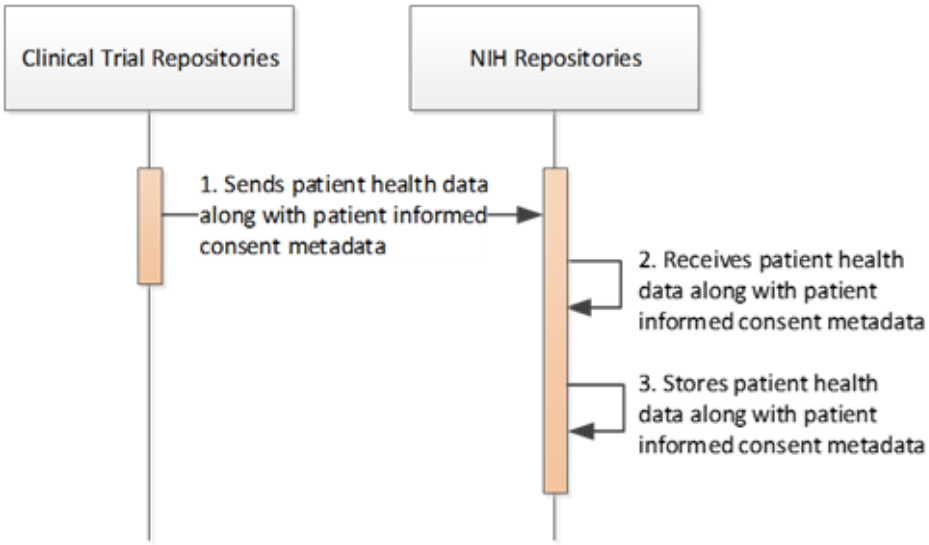


Table 29: Base Flow of Consent Scenario 4 Part 2: Clinical Trial Sends Information to Repositories

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Clinical Trial Repositories	Data Source	Sends patient health data along with patient informed consent metadata	Patient health data along with patient informed consent metadata	Patient health data along with patient informed consent metadata	Information Interchange
2	NIH Repositories	Data Receiver	Receives patient health data along with patient informed consent metadata	Patient health data along with patient informed consent metadata	Patient health data along with patient informed consent metadata	Information Interchange

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
3	NIH Bio & Data Repositories	Data Source	Stores patient health data along with patient informed consent metadata	Patient health data along with patient informed consent metadata	Stored patient health data along with patient informed consent metadata	System

Table 30: System Requirements of Consent Scenario 4 Part 2: Clinical Trial Sends Information to Repositories

System	System Requirement
NIH Biospecimen & Data Repositories	Stores patient health data along with patient informed consent metadata

6.4.3 Part 3: Secondary Researchers Monitor Clinical Trial Inputs into Repositories and Re-Contact Alice For Secondary Research

A secondary research group associated with the Ocular Immunology and Uveitis Research Foundation (OIUF) accesses Alice's de-identified data.[14] The researchers detect an increase in anti-immune reactions that may be compromising Alice's ocular immunity privilege. As a result of the secondary access, Alice's Recruitment Counselor receives a consent receipt that is also included in her patient portal.

The OIUF contacts and requests that Alice's OBT/OPM Recruitment Counselor give her information about being genetically predisposed to a rare vision disease, Sympathetic Ophthalmia/Uveitis.[15]

Since Alice has consented to being re-contacted via her Recruitment Counselor to participate in further research, she is re-contacted by her OBT Recruitment Counselor and signs a Global Registry of Rare Disease (GRDR) Informed Consent to enroll in the clinical trial.[16] As part of her participation in the OIUF clinical trial, the OBT/OPM repository sends her clinical data, biospecimens, and consent metadata to the secondary researcher forming a virtual.

---

[14] Their translational research focuses on rare ocular diseases, some of which are related to ocular trauma. Detection requires monitoring biomarkers in a patient's ocular data for signs of pathological immunological reactions to trauma. This research study is testing the suppression of her ocular immune privilege, which may cause acute anterior uveitis (AAU), the most common form of uveitis, by her genetic predisposition for autoimmune diseases related to HLA-B27 or PTPN22 genotype.

15 Sympathetic Ophthalmia (SO) or Sympathetic uveitis is a bilateral diffuse granulomatous uveitis (a kind of inflammation) of both eyes following trauma to one eye. It can leave the patient completely blind. Symptoms may develop from days to several years after a penetrating eye injury. https://en.wikipedia.org/wiki/Sympathetic_ophthalmia

[16] The computable version of this consent form utilizes the standard Global Rare Diseases Patient Registry and Data Repository® (GRDR®) Common Data Elements (CDE), which are also used to populate the questionnaires, survey instruments, case report forms, and other research material that are collected in the seventeen Rare Diseases Human Biospecimens/Biorepositories (RD-HuB). By using standard CDEs, GRDR ensures interoperability and correctness of the information that will be used multiple times. Using CDEs in combination with other standard codes for consent directives could enable computable enforcement of the patient's GRDR Informed Consent and the Data Use Certification for the NIH/NCATS GRDR Program Terms and Conditions when researchers are granted access to patient level data.

Figure 14: Sequence Diagram of Consent Scenario 4 Part 3: Secondary Researchers Monitor Clinical Trial Inputs into Repositories and Re-Contact Alice for Secondary Research

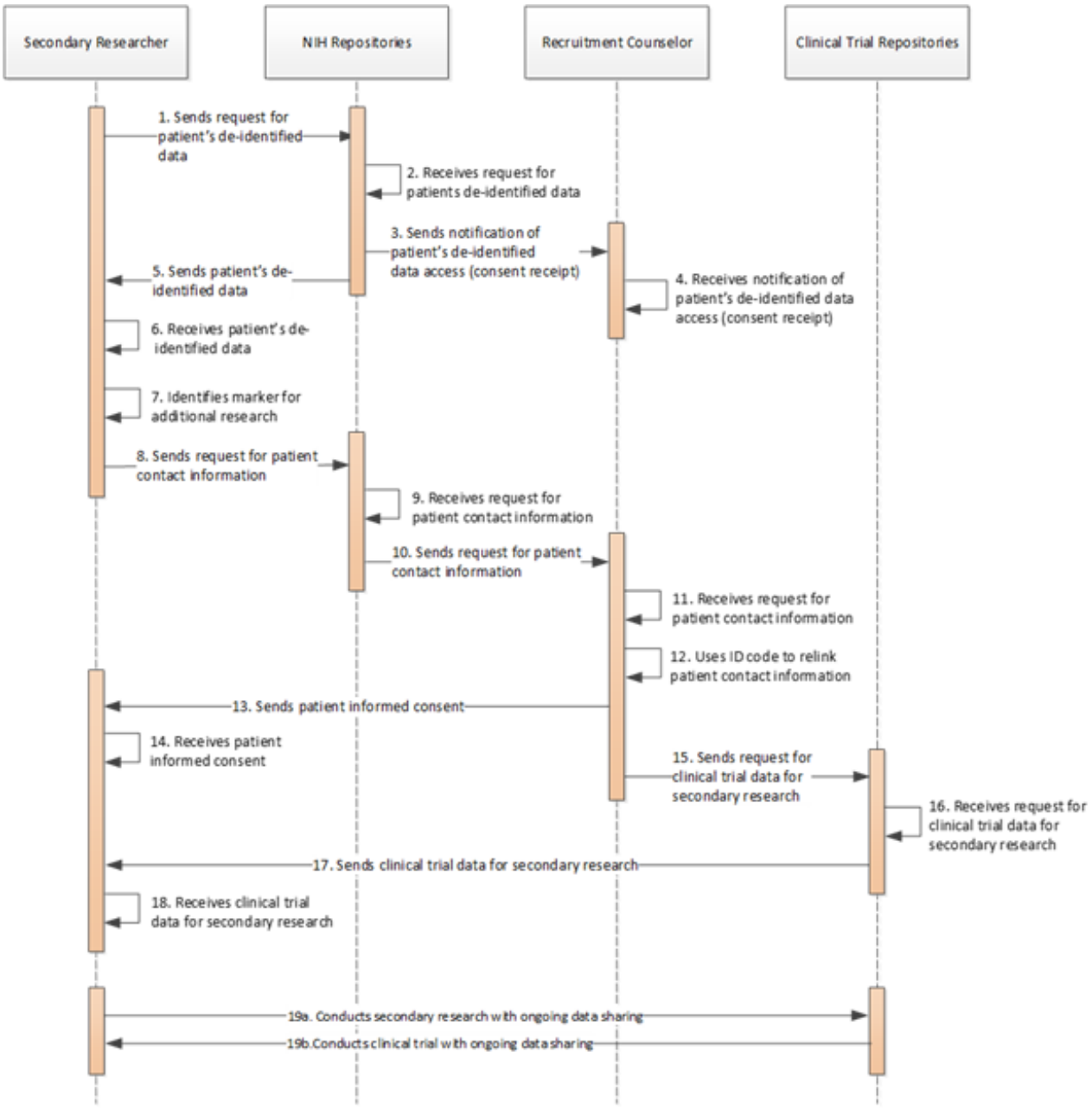


Table 31: Base Flow of Consent Scenario 4 Part 3: Secondary Researchers Monitor Clinical Trial Inputs into Repositories and Re-Contact Alice for Secondary Research

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
1	Secondary Researcher	Data Requester	Sends request for patient's de-identified data	Request for patient's de-identified data	Request for patient's de-identified data	Information Interchange
2	NIH Repositories	Data Receiver	Receives request for de-identified data	Request for patient's de-identified data	Request for patient's de-identified data	Information Interchange
3	NIH Repositories	Data Source	Sends notification of de-identified data access (consent receipt)	Request for patient's de-identified data	Notification of de-identified data access	Information Interchange
4	Recruitment Counselor	Data Receiver	Receives notification of de-identified data access (consent receipt)	Notification of de-identified data access	Notification of de-identified data access	Information Interchange
5	NIH Repositories	Data Source	Sends de-identified data	De-identified data	De-identified data	Information Interchange
6	Secondary Researcher	Data Receiver	Receives de-identified data	De-identified data	De-identified data	Information Interchange
7	Secondary Researcher	Data Source	Identifies marker for additional research	De-identified data	Marker for additional research	System
8	Secondary Research	Data Source	Sends request for patient contact information	Marker for additional research	Request for contact information	Information Interchange
9	NIH Repositories	Data Receiver	Receives request for patient contact information	Request for contact information	Request for contact information	Information Interchange
10	NIH Repositories	Data Requester	Sends request for patient contact information	Request for contact information	Request for contact information	Information Interchange
11	Recruitment Counselor	Data Receiver	Receives request for patient contact information	Request for contact information	Request for contact information	Information Interchange
12	Recruitment Counselor	Data Source	Uses ID code to relink patient contact information	Request for contact information	Relinked patient contact information	System
13	Recruitment Counselor	Data Source	Sends patient informed consent	Relinked patient contact information	Patient informed consent	Information Interchange
14	Secondary Researcher	Data Receiver	Receives patient informed consent	Patient informed consent	Patient informed consent	Information Interchange

Step #	Actor	Role	Event/Description	Inputs	Outputs	Type of Requirement
15	Recruitment Counselor	Data Requester	Sends request for clinical trial data for secondary research	Request for clinical trial data	Request for clinical trial data	Information Interchange
16	Clinical Trial Repositories	Data Receiver	Receives request for clinical trial data	Request for clinical trial data	Request for clinical trial data	Information Interchange
17	Clinical Trial Repositories	Data Source	Sends clinical trial data	Request for clinical trial data	Clinical trial data	Information Interchange
18	Secondary Researcher	Data Receiver	Receives clinical trial data	Clinical trial data	Clinical trial data	Information Interchange
19a	Secondary Researcher	Data Source	Conducts secondary research with ongoing data sharing	Ongoing data sharing	Ongoing data sharing	System
19b	Clinical Trial Repositories	Data Source	Conducts clinical trial with ongoing data sharing	Ongoing data sharing	End Flow	System

Table 32: System Requirements of Consent Scenario 4 Part 3: Secondary Researchers Monitor Clinical Trial Inputs into Repositories and Re-Contact Alice for Secondary Research

System	System Requirement
Secondary Researcher	Identifies marker for additional research
Recruitment Counselor	Uses ID code to relink patient contact information
Secondary Researcher	Conducts secondary research with ongoing data sharing
Clinical Trial Repositories	Conducts clinical trial with ongoing data sharing

7.0 High Level Business Issues and Obstacles

- Limited experience in the healthcare industry with electronically making data sharing decisions based on a combination of variables for granular choice that addresses patient preferences for data sharing based upon diagnosis, source of treatment, type of treatment, data recipient, and purpose of data use
- Standards to support the communication of data sharing preferences for research are still under development
- There are complex and variable federal, state, and local laws and regulations for conducting research and capturing consent that must also be electronically represented appropriately[17]
- Laws and regulations are subject to change and will require that electronic workflows be updated based on the applicable law at a point in time
- Patients may provide conflicting consent directives that will be difficult to arbitrate electronically
- There is little experience with direct patient control of electronic data sharing preferences
- There is emerging experience with the automated enforcement of prohibitions on re-disclosures
- Electronic consent management systems must be properly configured to avoid inadvertently providing sensitive information in a consent directive or transmission wrapper
- Electronic consent management systems must be properly configured to avoid providing responses to queries that inadvertently contain sensitive information
- Ownership of institutions may change resulting in changes to privacy policy and the sharing of accumulated data in ways that are unanticipated by consenters

8.0 Dataset Considerations

8.1 Core Consent Directive Data Requirements

The data elements or data groups in the table below can address the variety of research consent directive exchanges described in Section 6: Research Scenarios. This list can be used to construct a consent directive document structure. An example of a consent directive document structure is included below this table. The types of consent directives that could be developed based on these data elements are listed below.

- Informed Consent
- HIPAA Research Authorization
- Compound Authorization
- Patient Right of Access Authorization for Research
- Broad Consent
- Derivatives [consent metadata] for all of the above

[17] ONC worked with the National Governors Association to understand the various complexities in state law to improve information flow between health care entities. https://www.healthit.gov/buzz-blog/privacy-and-security-of-ehrs/roadmap-states-addressing-privacy-policy-barriers-availability-flow-electronic-health-information

Table 33: Dataset Requirements for Research Consent Directives

Element #	Data Element/Group	Description	Cardinality
1	**Consent Directive Envelope Security Label**	Protects the consent directive content from unauthorized access.	0..*
2	**Research Consent Directive**	The standard, interoperable, and computable record of: (1) A study subject's authorization for the collection, access, use and disclosure of protected health information for research purposes, for example in a HIPAA Authorization for Research. (2) A study subject's "informed" consent, assent, dissent to, or the acknowledgement of the subject's participation in the research study as proposed in the consent directive, which may involve certain activities performed by authorized agents on the subject, the subject's biospecimen, and/or the subject's health information; or performed by the subject, such as responding to surveys, self-administering study procedures or making study observations, and collecting patient reported health information.	
3	**Consent Directive Identifier/Version**	Unique "business" identifier for this research consent directive content.	0..1
4	**Consent Directive Status**	Indicates the current state in the lifecycle of this research consent directive. Examples include "proposed", "active", "amended", and "revoked".	0..1
5	**Consent Directive Content Use**	Indicates whether this research consent directive content is used as a template, a form, is the instance, or is a derivative of the instance used to convey the minimal set of information needed for consent directive management.	0..1
6	**Consent Directive Issued**	This is the date/time at which this research consent directive is signed, which may precede period during which this research consent directive is in effect.	0..1
7	**Consent Directive Applies**	The period during which this research consent directive is in effect. If the expiration time is not known when this consent directive instance is recorded, then only the start date/time is valued.	0..1
8	**Consent Directive Expiration Type**	Codes indicating the triggering event(s) for expiration when the end date is not known. The event could be indeterminate as in the case when the consent directive explicitly states that there's no expiration date.	0..*
9	**Consent Directive Authority**	Indicates a country, state, or other region where the study is taking place.	0..*
10	**Consent Directive Domain**	IRB institution overseeing the research or the funding organization.	0..*
11	**Consent Directive Site**	The IRB site number, clinic, hospital, and/or other healthcare location that is participating in the study.	0..*
12	**Consent Directive Type (move before subject)**	Indicates the general category of research consent directive, e.g., HIPAA Authorization for Research, an Informed Consent, or a Compound Authorization.	0..1

Element #	Data Element/Group	Description	Cardinality
13	**Consent Directive Subtype**	Indicates a more specific category of research consent directive, e.g., HIPAA Research Authorization, or an FDA or Broad Informed Consent. May be a compound of informed consents for several research studies and combined with a HIPAA Research Authorization. Additionally, there are Informed Consents modified for specific types of research such as NCATS, Genetic and Rare Disease Registry, and Biospecimen related studies.	0..*
14	**Consent Directive Subject [Offeree/Grantor]**	The focal subject named in the research consent directive as a target of the activity proposed in the research consent directive, such as the collection, access, use, or disclosure of personal health information or the proposed study activities involving the subject.	0..1
15	**Consent Directive Offeror/Grantee**	Person obtaining consent. For informed consent, this is likely a study team member acting on behalf of the study Principle Investigator. For a HIPAA Authorization for Research, this is likely a representative of a covered entity or business associate, which is the custodian of the subject's protected health information.	0..1
16	**Consent Directive Proposal**	The research study description and purpose, which is "offered" to a prospective study subject and is inclusive of all the terms within the consent directive. The proposal includes any optional terms not accepted by the consenter; and terms in which the consenter has negotiated an additional opt-out exception (do not disclose to Dr. Bob except in an emergency) or opt-in restriction (do not disclose to my mother, the nurse). The proposal is the top-level term, which is inclusive of all the pertinent elements related to a term, and must be the grouper for any additional terms, which may themselves group, i.e., the proposal contains all terms in the consent directive.	0..1
17	**Consent Directive Proposal Title**	Title of a research study.	0..*
18	**Consent Directive Proposal Category**	Codes categorizing the type of study such as investigational vs. observational, type of blinding, type of randomization, safety vs. efficacy, etc.	0..*
19	**Consent Directive Proposal Topic**	Detailed description and statement of the purpose and objectives of a research study, clinical trial, or secondary use that the consenter is requested to consider and to which the consenter may consent or dissent.	0..1
20	**Consent Directive Proposal Prose link ID**	Links to consent directive form response proposal prose.	0..1
21	**Consent Directive Proposal Answer link ID**	Links to a consent directive form response answer selected by the consenter which would typically be an indicator that the consenter understood the research proposal.	0..1

Element #	Data Element/Group	Description	Cardinality
22	**Consent Directive Decision**	Specifies the type of consent directive decision, acknowledgement, or deferral of decision that the study subject makes about the consent directive proposal. The consent directive decision at the proposal level may be modified at the proposal's term level where the subject has the opportunity to have more granular choice, e.g., of optional choices such as the type of information that the study may collect, access, use, or disclose; re-contacting or being informed of clinically actionable findings; and participation in future or secondary use of information/biospecimens.	0..1
23	**Consent Directive Decision Mode**	The mode by which the research subject indicates consent, assent, or dissent to the proposal. Examples include non-verbal, verbal, click on graphic user interface choice box, simple mark on hard copy consent form, scanned wet signature, or some type of electronic or digital signature.	0..*
24	**Consent Directive Decision Prose link ID**	Links to Consent Directive Form decision question or notice required legal prose under research policies such as: HIPAA, Common Rule, FDA, Title 38 Section 7332, and 42 CFR Part 2.	0..*
25	**Consent Directive Decision Answer linkID**	Links to the consenter's Consent Directive Response decision or acknowledgement of a notice required legal prose under research policies such as: HIPAA, Common Rule, FDA, Title 38 Section 7332, and 42 CFR Part 2.	0..1
26	**Consent Directive Term**	The research consent directive term is used to list the component provisions of the research consent directive proposal. See Consent Directive Term Topic for details. From a modeling perspective, the Consent Directive Proposal is the top-level term, which groups any additional terms and has all the sub-elements of a term including agent and action. Subsumed terms can iterate and can be grouped to convey the elements required or optional under the consent directive policy.	0..*
27	**Consent Directive Term Proposal Group**	This is where terms related to the proposal are elaborated such as consent to and withdrawal from the study being voluntary without impacting any other rights/benefits albeit that assets already contributed cannot be recalled. Risks, benefits, compensation, re-contacting, and being informed of research results and clinically actionable findings. Includes the consenter's term decision, which is specific to the term, in which case the consent directive decision must be either an opt-in with restrictions, or less likely, an opt-out with exceptions.	0..1

Element #	Data Element/Group	Description	Cardinality
28	**Consent Directive Term Proposal**	The statement of description of a required or additional consent element based on the type of research consent directives that are applicable to the consent directive proposal. Each term proposal is "offered" to a prospective study subject and is inclusive of any sub-terms grouped by this term, even where an optional sub-term is not accepted by the consenter or where the consenter has negotiated an additional opt-out exception. For example, a subject may dissent from re-contact or limit the types of secondary research purposes to those related to a specific disease. For HIPAA Authorization for Research, Common Rule, FDA, and Broad informed consent, there shall be a term for each consent element required by law. Examples of HIPAA Authorization for Research required elements include: Description of data used or disclosed, persons authorized to disclose, others that may be contacted for disclosure, purpose of disclosure, expiration date or event, signature and date, patient's right of revocation, procedure and exceptions, conditioning of services on authorization, and potential for re-disclosure. Examples of informed consent required elements include: research purpose, description, benefits, and alternate courses of action; statement that participation is voluntary; statement of research results, such as protection of confidentiality, compensation; and subject's rights. Additional consent elements, which must be included when appropriate, shall be conveyed in a term. Examples include description and probability of risks such as inconveniences or side effects, description of compensation, and statements about circumstances in which the investigators may terminate or a subject may discontinue participation. Terms describing banked specimens for future research must be clearly addressed whether participation is conditioned or not on consenting to these terms.	0..1
29	**Consent Directive Term Proposal Title**	Title of a research study or research provision if there is no other documentation that includes this information and can be referenced.	0..*
30	**Consent Directive Term Proposal Category**	Codes categorizing the type of study such as investigational vs. observational, type of blinding, type of randomization, safety vs. efficacy, etc.	0..*
31	**Consent Directive Term Proposal Topic**	A high-level statement or description of what the consent directive term proposal is about, for example "risks" or "banked specimens for future research." May be more useful where there are a group of sub-terms.	0..*
32	**Consent Directive Term Proposal Prose link ID**	Links to Consent Directive Response term level proposal.	0..*

Element #	Data Element/Group	Description	Cardinality
33	**Consent Directive Proposal Term Value link ID**	Links to Consent Directive Response term level proposal answer selected by the consenter. Typically, would be an indicator that the consenter understood the research proposal.	0..*
34	**Consent Directive Term Decision**	Specifies the type of consent directive decision, acknowledgement, or deferral of decision that the study subject makes about the consent directive proposal. The consent directive decision at the proposal level may be modified at the proposal's term level where the subject has the opportunity to have more granular choice, e.g., of optional choices such as the type of information that the study may collect, access, use or disclose; re-contacting or being informed of clinically actionable findings; and participation in future or secondary use of information/biospecimens.	0..1
35	**Consent Directive Term Decision Mode**	The mode by which the research subject indicates consent, assent, or dissent to the proposal. Examples include non-verbal, verbal, click on graphic user interface choice box, simple mark on hard copy consent form, scanned wet signature, or some type of electronic or digital signature.	0..*
36	**Consent Directive Decision Prose link ID**	Links to Consent Directive Form decision question or notice required legal prose under research policies such as: HIPAA, Common Rule, FDA, Title 38 Section 7332, and 42 CFR Part 2.	0..*
37	**Consent Directive Decision Answer link ID**	Links to the consenter's Consent Directive Response decision or acknowledgement of a notice required legal prose under research policies such as: HIPAA, Common Rule, FDA, Title 38 Section 7332, and 42 CFR Part 2.	0..1
38	**Consent Directive Term Asset**	The consenter's rights or "grants", such as the right to privacy and control of physical and mental capacities; participation in research activities related to the protocol; property such as the donation of PHI from multiple sources including information collected and stored by internet providers, devices, EHRs and PHRs, from Patient Generated Health Data [PGHD], and responses during assessments and to surveys; donation of time, personal resources, and encumbrances such as the inconveniences resulting from donation and participation; undertaking of risks related to participation such as bodily harm and the potential loss of PHI and personal information confidentiality.	0..*
39	**Consent Directive Term Asset Period**	Specification of a time period related to the existence of the asset. E.g., an episode of care, a lifetime medical record, or device information gathered in last year.	0..1
40	**Consent Directive Term Asset Use Period**	Period in which the research consent directive stipulates that the asset will be used for research purposes. This is not necessarily equivalent to the period in which the research consent directive is in effect.	0..1
41	**Consent Directive Term Asset Class**	Code indicating the format and syntax of the asset, e.g., a consult note scan or a DICOM image.	0..1

Element #	Data Element/Group	Description	Cardinality
42	Consent Directive Term Asset Code	Code indicating the asset's characterization in some domain. E.g., claims data for a procedure may be characterized by a CPT (Current Procedural Terminology) code. Lab orders may be indicated by LOINC (Logical Observation Identifiers Names and Codes) codes.	0..*
43	Consent Directive Term Asset Context	Code indicating the scope and context of a specific data reference. E.g., an episode of care may also include coded information about the provider. In the alternative, a procedure reference may be included in an episode of care.	0..*
44	Consent Directive Term Asset Reference	Reference to the specific asset.	0..*
45	Consent Directive Term Asset Security Label	The security label that governs the custodian and the recipient's permissible actions on this asset as specified by this research consent directive.	0..*
46	Consent Directive Term Asset Value	The consideration exchanged for the asset granted to a Grantor. For research consent directives, this is the compensation that a study subject may receive for consent to participate. From a modeling perspective, the value may be the net of quantity and unit price values.	
47	Consent Directive Term Asset Prose linkID	Link to the Consent Form Prose Object item describing the asset, including the types of privacy, confidentiality, and security controls, data use limitations, de-identification method, restrictions on researcher access to personal information, etc.	0..*
48	Consent Directive Term Asset Value linkID	Link the Consent Response item answer.	0..1
49	Consent Directive Term Agent	Who or what is controlled by this consent. Use group to identify a set of actors by some property they share. For example, the Principal Investigator, clinicians involved with a clinical trial, researchers, recruitment counselors, contacts for questions, concerns, revocation; an IRB, a Privacy Committee, etc.	0..*
50	Consent Directive Term Agent Actor	Who or what is controlled by this consent. Use group to identify a set of actors by some property they share.	0..1
51	Consent Directive Term Agent Role	How the individual is involved in the resources content that is described in the research consent directive.	0..1
52	Consent Directive Term Action Type	Code indicating the action stipulated in the research consent directive.	0..*
53	Consent Directive Term Action Reason	Rationale for the action.	0..*
54	Consent Directive Term Valued Item Group	Ability to value the study subject's contributed asset in terms of altruism or compensation.	0..*

Element #	Data Element/Group	Description	Cardinality
55	**Consent Directive Signer**	Signatory to the consent directive, which are either: (1) The research subject/proxy consent directive decision maker who (i)consents, assents, or dissents to the consent directive proposal as indicated in the consent directive decision; or (ii) withdraws an earlier consent or assent to the consent directive proposal. (2) The person that obtained the consent directive such as a research study principal investigator or a study representative such as the recruitment counselor who sign a consent directive as the "counterparty."	0..*
56	**Consent Directive Signer Type**	The research subject/proxy who is the consent directive decision maker; or Grantee research principal investigator/proxy Signer role.	0..1
57	**Consent Directive Signer Party**	Reference to specific information about the signer. Consent Directive signer contact information. For example, may reference the research study subject who is the grantor or a proxy. May reference the person who obtained the subject's decision, which may be a consent, assent, dissent, or withdrawal; or a principal investigator whose reference is contained in the consent directive proposal or listed as an agent in one of the terms.	0..1
58	**Consent Directive Signer Signature**	Legally recognized and honored signature within the research jurisdiction of the grantor and grantee.	0..1
59	**Consent Directive link Reference/Attachment**	The location of the consent directive response to which this consent directive may be linked.	0..1
60	**Consent Directive Policy Reference/Attachment**	A link or representation of the jurisdictional, organizational, or healthcare consumer informed consent policies.	0..*
61	**Consent Directive Legally Binding Reference/Attachment**	This is the legally binding consent directive that has standing in a court of law because it has all the aspects required of a legal contract. It obligates the grantee to comport with the proposal offered to the grantor concerning the assets granted in the contract, and requires the grantee to comply with various obligations and refrains enumerated in the contract at the header and term level. Links to or represents an executed or post executed consent directive instance. It is the source for a consent directive derivative used for managing executed and post-executed consent directive workflows, such notification of a revocation. When the instance of a consent directive is a derivative, this is the source of the business identifier of the base consent directive from which the derivative is sourced. See Consent Directive content use element #5.	0..1
62	**Consent Directive Rule Content**	Links to or represents a rules engine consumable equivalent of the legally binding research consent directive or a derivative of the research consent directive used for automated access control. The rule combines the header and term components into one rule.	0..1

8.2 Consent Document Exchange Datasets

The following datasets are intended to capture the information in a query and response for consent location as well as a query for a consent directive. While this use case is neutral to consent storage and retrieval architecture, a potential implementer may leverage these in a manner that is compatible with their architecture.

Table 34: Dataset Requirements Query for Consent Location

Data Element	Data Element Description
Patient Identifier	Identifier for the Patient who is the subject of the consent
Patient Name	Name of the Patient who is the subject of the consent
Patient Gender	Male/Female
Patient Date of Birth	Birth date of the Patient
Patient Address	Address of the Patient
Requester ID	The unique identifier for the person or organization requesting the Consent Directive
Requester Name	Name of the person requesting the Consent Directive
Requester Organization	Organization that the requester is associated with or the organization that is requesting the consent
Requester Address	Address of the person or organization requesting the data
Requested User(s)	Person, organization, or role permitted to use the data
Requested Purpose(s)	Purpose for which the data may be used
Information Requested	Information that is being requested (query you want answered)
Requester Role	Role of individual requesting patient data
Consent Originator ID	Unique identifier for the organization that is responsible for the consent
Consent Originator Organization	Name of the organization that is responsible for the consent
Community ID	An identifier that is used to request documents across HIE's
Document ID	An identifier for the patient consent directive document

Table 35: Dataset Requirements Response for Consent Location

Data Element	Data Element Description
Consent ID	The unique identifier associated with the Consent Directive
Patient Identifier	Identifier for the patient who is the subject of the consent
Patient Name	Name of the patient who is the subject of the consent
Consent Originator ID	Unique identifier for the organization that is responsible for the consent
Consent Originator Organization	Name of the organization that is responsible for the consent
Consent Directive Location	Identifier or other information that will allow the requester to determine where to send the query for the Consent Directive

Data Element	Data Element Description
Denial Code	An indicator that the query recipient is unable to respond to the query The content of this field should not indirectly expose additionally protected Patient data

Table 36: Dataset Requirements Query for the Consent Directive

Data Element	Data Element Description
Consent ID	The unique identifier associated with the Consent Directive
Patient Identifier	Identifier for the patient who is the subject of the consent
Patient Name	Name of the patient who is the subject of the consent
Patient Gender	Male/Female
Patient Date of Birth	Birth date of the patient
Patient Address	Address of the patient
Requester ID	The unique identifier for the person or organization requesting the Consent Directive
Requester Name	Name of the person requesting the Consent Directive
Requester Organization	Organization that the requester is associated with or the organization that is requesting the consent
Requester Address	Address of the person or organization requesting the data
Requested User(s)	Person, organization, or role permitted to use the data
Requested Purpose(s)	Purpose for which the data may be used
Information Requested	Information that is being requested (query you want answered)
Requester Role	Role of individual requesting patient data
Type of Consent Requested	A code indicating the type of Consent Directive that is of interest to the requester
Consent Originator ID	Unique identifier for the organization that is responsible for the consent
Consent Originator Organization	Name of the organization that is responsible for the consent

9.0 Candidate Standards for Consideration

The following standards could potentially be leveraged by an implementer to exchange basic choice for research consent information. The data elements in Section 10: Dataset Considerations are reflected with varying degrees across the candidate standards listed below.

9.1 Candidate Standards for Syntax

- HL7 Implementation Guide for Clinical Document Architecture (CDA)®, Release 2: Consent Directives, Release 1
- HL7 Fast Healthcare Interoperability Resources Specification (FHIR®), Release 3 STU, Release 4 v4.0.1 (Mixed Normative and STU)
  - FHIR® Security Labels
  - FHIR® Consent Resource – requires FHIR Provenance to convey signature
  - FHIR® Contract – needed for informed consent
  - FHIR® Privacy Consent Directive Implementation Guide
  - FHIR® ResearchStudy – for informed consent
  - FHIR® ResearchSubject – references FHIR Consent but would need FHIR Provenance to reference into ResearchSubject in order to include a signature
  - FHIR® PlanDefinition – this can be used to describe the actual protocol in a research study
  - FHIR® Questionnaire – for implementers that want to use a standard to develop a consent directive form
  - FHIR® QuestionnaireResponse
  - FHIR® Bundle – Need this to "bundle" FHIR Resources needed for Informed Consent
- Integrating the Healthcare Enterprise (IHE) Basic Patient Privacy Consents
- Integrating the Healthcare Enterprise (IHE) Advanced Patient Privacy Consents
- NIH Consent Templates – Used for consent metadata
  - Informed Consent
    - **2 Questions** - Contains data elements that document the participant's/subject's consent to participate in the clinical research protocol.
  - Informed Consent and Enrollment
    - **6 Questions** - Contains data elements that document the date of certain study milestones, such as informed consent, study enrollment, and randomization, which are necessary from both an administrative and human subjects' protection standpoint.
  - Consent National Cancer Institute (NCI) Standard Template
    - **6 Questions** - The collection of Common Data Elements (CDEs) can be used in the consent module.
  - Consent Withdrawal NCI Standard Template
    - **6 Questions** - The collection of CDEs can be used in the consent withdrawal module.
  - Consent Withdrawal Specimen NCI Standard Template
    - **5 Questions** - The collection of CDEs can be used in the specimen consent withdrawal module.
  - Consent Withdrawal Quality of Life Study NCI Standard Template
    - **7 Questions** - The collection of CDEs can be used in the study consent withdrawal module quality of life study.

9.2 Candidate Standards for Vocabulary

- NIH Common Data Elements Global Rare Disease Registry Codes
- HL7 Healthcare Privacy and Security Classification System (HCS), Release 1
- Global Alliance for Genomic Health Data Use Limitation "Consent Codes"[18]

[18] Dyke SO, Philippakis AA, Rambla De Argila J, et al. Consent Codes: Upholding Standard Data Use Conditions. PLoS Genet. 2016;12(1):e1005772. Published 2016 Jan 21. doi:10.1371/journal.pgen.1005772

10.0 Appendices

10.1 Appendix A: Related Use Cases and Specifications

Health Level Seven, Consent Directive: HL7 Use Cases Retrieved from http://wiki.hl7.org/index.php?title=Consent_Directive_Use_Cases

Direct Project, Direct Project's Implementation Group User Stories, Retrieved from http://wiki.directproject.org/User+Stories

Health Information and Management Systems Society, Emergency Responder with Patient Privacy Protection Retrieved from http://www.interoperabilityshowcase.org/himss10/docs/summary/HIMSSInteroperabilityShowcaseDocuments/ACT%2018_Emergency%20Responder%20with%20Patient%20Privacy%20Protection.pdf

Health Information and Management Systems Society, HIE Core Services, Retrieved from http://www.interoperabilityshowcase.org/himss10/docs/summary/HIMSSInteroperabilityShowcaseDocuments/ACT%2027_HIE%20Core%20Services.pdf

Standards and Interoperability Framework, Transitions of Care (ToC), Retrieved from http://wiki.siframework.org/ToC+-+Final+Use+Case

Standards and Interoperability Framework, Data Segmentation for Privacy (DS4P), Retrieved from http://wiki.siframework.org/Data+Segmentation+for+Privacy+Homepage

American Health Information Committee (AHIC)—– US Department of Health and Human Services, AHIC Consumer Preferences Gap Use Case, Retrieved from http://healthit.hhs.gov/portal/server.pt?open=512&objID=1202&&PageID=15667&mode=2&in_hi_userid=10732&cached=true

Healthcare Information Technology Standards Panel Emergency Common Alerting Protocol Component, HITSP CAP 143 – Manage Consumer Preference and Consents, Retrieved from http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=1afe3fc9-4d31-4597-968d-afe7bf183197

10.2 Appendix B: References

American Society for Testing and Materials (ASTM), ASTM E2369 - 05e2 Standard Specification for Continuity of Care Record (CCR), Retrieved from http://www.astm.org/Standards/E2369.htm

Cavoukian Ann Ph.D., Privacy by Design, Information & Privacy Commissioner of Ontario, Canada, Retrieved from https://www.ipc.on.ca/wp-content/uploads/resources/7foundationalprinciples.pdf

Congressional Research Service Reports for the People (Open CRS), Enforcement of the HIPAA Privacy and Security Rules, Retrieved from http://opencrs.com/document/RL33989/

Council for Affordable Quality Healthcare (CAQH), CORE: Advancing Electronic Data Exchange and Connectivity, Retrieved from http://www.caqh.org/benefits.php

Health Level Seven International Inc (HL7), Version 2 Product Suite (V2), Retrieved from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185

Health Level Seven International Inc (HL7), Clinical Document Architecture Release 2, Retrieved from http://www.hl7.org/implement/standards/cda.cfm

Health Level Seven International Inc. (HL7), HL7 Implementation Guide for Clinical Document Architecture, Release 2, Retrieved from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=91

Health Level Seven International Inc. (HL7), Green CDA Project (HL7 Wiki), Retrieved from http://wiki.hl7.org/index.php?title=GreenCDA_Project

Healthcare Information Technology Standards Panel, HITSP: TP30: Manage Consent Directives Transaction Package1.3, Retrieved from http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=2&PrefixNumeric=30

HIT Standards Committee - Metadata Analysis Power Team, HITSC 2011, Retrieved from http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_12811_954902_0_0_18/metadata-analysis-power-team-06-22-11.pdf

Integrating the Healthcare Enterprise (IHE), Audit Trail and Node Authentication (ATNA) Integration Profile (IHE wiki), Retrieved from http://wiki.ihe.net/index.php?title=ATNA

Integrating the Healthcare Enterprise (IHE), Cross-Enterprise Document Sharing (XDS), IHE wiki, Retrieved from http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing

Integrating the Healthcare Enterprise (IHE), Cross-Enterprise User Assertion (XUA), IHE Wiki, Retrieved from http://wiki.ihe.net/index.php?title=XUA

Integrating the Healthcare Enterprise (IHE), Cross-Community Access (XCA), IHE Wiki, Retrieved from http://wiki.ihe.net/index.php?title=Cross-Community_Access

Integrating the Healthcare Enterprise (IHE), Cross-Community Patient Discovery (XCPD), IHE Wiki, Retrieved from http://wiki.ihe.net/index.php?title=XCPD

Integrating the Healthcare Enterprise (IHE), Enabling Document Sharing Using IHE Profiles, IHE IT Infrastructure White Paper, 2012, Retrieved from http://www.ihe.net/Technical_Framework/upload/IHE_ITI_White-Paper_Enabling-doc-sharing-through-IHE-Profiles_Rev1-0_2012-01-24.pdf

Integrating the Healthcare Enterprise (IHE), Document Encryption (DEN), IHE Wiki, Retrieved from http://wiki.ihe.net/index.php?title=DEN

Integrating the Healthcare Enterprise (IHE), Consistent Time Integration Profile (CT), Retrieved from http://wiki.ihe.net/index.php?title=Consistent_Time

Integrating the Healthcare Enterprise (IHE), Cross-enterprise Document Media Interchange, Retrieved from http://wiki.ihe.net/index.php?title=Cross-enterprise_Document_Media_Interchange

Integrating the Healthcare Enterprise (IHE), Cross-enterprise Document Reliable Interchange, Retrieved from http://wiki.ihe.net/index.php?title=Cross-enterprise_Document_Reliable_Interchange

Integrating the Healthcare Enterprise (IHE), Metadata Analysis Power Team at 6/22 HITSC Meeting, Basic Patient Privacy Consents, Retrieved form http://wiki.ihe.net/index.php?title=Basic_Patient_Privacy_Consents

Integrating the Healthcare Enterprise (IHE), Patient Demographics Query (IHE Wiki), Retrieved from http://wiki.ihe.net/index.php?title=Patient_Demographics_Query

Integrating the Healthcare Enterprise (IHE), Patient Identifier Cross-Referencing (IEH Wiki), Retrieved from http://wiki.ihe.net/index.php?title=Patient_Identifier_Cross_Referencing

Integrating the Healthcare Enterprise (IHE), Security and Privacy through IHE Profiles, IHE IT Infrastructure White Paper, 2008, Retrieved from http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Whitepaper_Security_and_Privacy_of_HIE_2008-08-22-2.pdf

Healthcare Security/Privacy, Moehrke. J., Weblog Article, 2011, Retrieved from http://healthcaresecprivacy.blogspot.com/2011/04/hit-standards-pcast-analysis-against.html

MITRE, Kairon Consents consent management system, Retrieved from http://sourceforge.net/projects/kaironconsents/

National Cancer Institute (NIC), Electronic Data and Security Framework (Wiki), Retrieved from https://wiki.nci.nih.gov/display/DSIC/Electronic+Data+Sharing+and+Security+Framework

National Cancer Institute Cancer Biomedical Grid, Retrieved from https://biospecimens.cancer.gov/relatedinitiatives/overview/caBig.asp

National Institute of Standards and Technology, NIST IR 7497 Security Architecture Design Process for Health Information Exchanges (HIEs), Retrieved from http://csrc.nist.gov/publications/nistir/ir7497/nistir-7497.pdf

National Institute of Standards and Technology, The Exchange of Health Information: Designing a Security Architecture to Provide Information Security and Privacy, 2010, Retrieved from http://csrc.nist.gov/publications/nistbul/november2010-bulletin.pdf

OASIS | Advancing open standards for the information society, Privacy policy profile of XACML v2.0, (2005), Retrieved from http://docs.oasis-open.org/xacml/2.0/access_control-xacml-2.0-privacy_profile-spec-os.pdf

The Office of Federal Register, Advanced Notice of Proposed Rulemaking on Metadata Standards, Retrieved from https://www.federalregister.gov/documents/2011/08/09/2011-20219/metadata-standards-to-support-nationwide-electronic-health-information-exchange

U.S Department of Health and Human Services, Privacy and Security, Retrieved from http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy_and_security/1147

U.S Government Printing Office - Code of Federal Regulations Part 35 the Self-Pay reg. HITECH §13405 and Proposed Rule 45 CFR Part 164.522(a) (1) (iv), Retrieved from http://edocket.access.gpo.gov/cfr_2009/octqtr/pdf/45cfr164.522.pdf

U.S Government Printing Office - Code of Federal Regulations, Title 38--Pensions, Bonuses, and Veterans' Relief, Retrieved from http://www.access.gpo.gov/nara/cfr/waisidx_03/38cfr3_03.html

U.S Government Printing Office - Code of Federal Regulations, Title 42--Public Health, PART 2--CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS - Retrieved from http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr2_02.html

10.3 Appendix C: Glossary

Definition	Description
42 CFR Part 2	Regulation that addresses the limitations on the release of patient information related to treatment in a Federally designated Alcohol and Drug Abuse Treatment Program (Reference 42 CFR § 2.13)
HITECH §13405 and Proposed Rule 45 CFR Part 164.522(a)(1) (iv)	Regulation that addresses the rights of patients to restrict the sharing of their health information with payers for self-pay care
Accounting of Disclosures	A listing of the disclosures of an individual's individually identifiable health information as limited by the HIPAA Privacy Rule (45 CFR § 164.528).
Additional Protected Patient Data	Patient healthcare data for which there are legal or regulatory constraints on the sharing of the data that go beyond those defined under HIPAA
Authorization	Method and form to secure permission from an individual for the use, or disclosure of individually identifiable health information, for any activity not specifically allowed without one. Uses and disclosures related to treatment, payment, and healthcare operations generally do not require a HIPAA authorization; but some non-healthcare related activities such as marketing do. Authorization is a new term used in the HIPAA Privacy Rule to denote an activity that has often been called a consent or a release (Per 42 CFR § 2.13 and 38 CFR § 1.475).
Consenter	A person or entity that has the legal authority to give permission to release health information.
Privacy Consent Directive	The record of one or more instruction(s) regarding an individual's privacy preferences that a Provider or organization agrees to or is required by law to enforce.
Consent Management	Consent management is a system, process or set of policies for allowing consumers and patients to determine what health information they are willing to permit their various care providers to access. It enables patients and consumers to affirm their participation in e-health initiatives and to establish privacy preferences to determine who will have access to their protected health information (PHI), for what purpose, and under what circumstances. Consent management supports the dynamic creation, management, and enforcement of consumer, organizational, and jurisdictional privacy directives.
Consent Subject	The person whose data is covered by the consent directive.
Diagnosis	Identification of a disease or condition by a scientific evaluation of physical signs, symptoms, history, laboratory test results, and procedures.
Disclosure	Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information. (HIPAA Section 160.103)

Definition	Description
Electronic Health Record (EHR)	A longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter—as well as supporting other care-related activities directly or indirectly via interface—including evidence-based decision support, quality management, and outcomes reporting.
Health Information Organization (HIO)	An organization that oversees, governs, and provides services to enable the exchange of health-related information among disparate healthcare information systems.
Healthcare Payers	Insurers, including health plans, self-insured employer plans, and third-party administrators, providing healthcare benefits to enrolled members and reimbursing organizations
Healthcare Provider	Refers to a person licensed, certified, or otherwise authorized or permitted by law to administer healthcare in the ordinary course of business or practice of a profession, including a healthcare facility. This includes primary care providers, other physicians, nurse-practitioners, physician assistants, etc.
Information Interchange Requirements	Specifies the transactions that are exchanged between systems and the role of each system in the exchange.
Patient	Person who is the recipient of healthcare services. For the purposes of the Data Segmentation Use Case the patient is the subject of the consent, consent directive, or authorization
Preference	A patient request regarding the use and disclosure of his or her health information. Preferences can be recorded but would not be enforced until there was an agreement by one or more providers to implement the preference.
Primary Care Physician (PCP)	A primary care physician is a generalist physician who provides care to the patient at the point of first contact and takes continuing responsibility for providing the patient's care.
Privacy Policy Model	An abstract representation of the variables or rules that can be associated with data to express the constraints that can be imposed on data sharing. The Policy Model may also be used to define and communicate constraints that emanate from sources other than patient preferences, e.g., laws, regulations, and organizational practices.
Protected Information	Information that is protected by a security policy. In healthcare, this includes a variety of clinical and administrative information that can be identified as belonging to a specific patient.
Provider	An individual clinician in a healthcare delivery setting.

Definition	Description
Provider Organizations	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, and other healthcare facilities
Specialist	A physician who has completed sub-specialty training beyond his or her initial residency.
System Requirements	Requirements internal to the system necessary to participate successfully in the transaction.
Treatment	The management and care of a patient condition in order to reduce or eliminate the adverse effects upon the patient