A Mixed Methods Study of Health Information Exchange Consent for Persons Living with Human Immunodeficiency Virus

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ABSTRACT

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Health information exchange (HIE) has the potential to improve care quality through improved information sharing and coordination of care. In Phase 1, a sociotechnical analysis was conducted at one HIV clinic to explore the interrelated factors that affect the consent of persons living with HIV (PLWH) to electronically share their protected health information (PHI) through a HIE. The findings of the sociotechnical analysis revealed that there is not a single solution that can adequately address the complex, interrelated issues that affect PLWH decision to electronically share PHI. Improvement in the consent process was selected as the target of intervention for Phase 2, which focused on designing and pilot testing a prototype HIE eConsent iPad app at the HIV clinic. A one-group post-test design examined if HIV clinic patients preferred the eConsent or the paper consent. Semi-structured interviews were used to assess overall comprehension of HIE after reading both consents. Over half of the participants favored eConsent as compared to paper consent. The proportion of participants who were able to verbalize essential components of HIE were as follows: more than one component – 35%, one component - 20%, and no component – 45%. While racially and ethnically diverse, the sample was well-educated (50% with a college degree); however, the low comprehension levels suggested that educational attainment was insufficient for HIE comprehension. A hybrid approach that integrates discussion with knowledgeable personnel and multimedia usage may be useful to convey complex information and facilitate HIE comprehension.

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Dedication

This dissertation is dedicated in loving memory to my grandparents,

Benjamin Ramos de la Cruz and Luz Marina Cruz-Maldonado Ramos.

Grandpa, you always stressed the importance of education and encouraged all of my academic endeavors. I love you and miss you both so much.

Chapter One

Human Immunodeficiency Virus (HIV) continues to be a critical public health issue that has affected the lives of millions globally, nationally, and locally (Ki-moon, 2013; Zeglin & Stein, 2015). Health information exchange (HIE) is one national initiative aimed at improving the quality of care and patient experience for persons living with HIV (PLWH) (Furukawa et al., 2014; W. C. Richardson et al., 2001). Health information exchange is the electronic sharing of an individual's protected health information (PHI) among healthcare providers with the intention of improving patient safety, healthcare quality, care continuity, and surveillance reporting (Patel et al., 2012; Williams, Mostashari, Mertz, Hogin, & Atwal, 2012). Data obtained through HIE can inform providers from non-affiliated healthcare organizations and institutions on how to make better treatment decisions on behalf of the patient. It can also be used to inform a patient's primary care clinician and specialists about medical encounters that occurred outside of their organization. Because of the perilous effects of HIV on individuals that are undiagnosed or out-of-care, there continues to be a need for the utilization of HIE as a means of optimizing outcomes through care coordination.

Nationally, there are varying levels of HIE utilization, and the mechanisms in which HIE consent is obtained varies from state to state. The amount of PHI an individual consents to share also greatly varies (M. Goldstein, 2010). No standard currently exists that guide how HIE consent is discussed or obtained (Ancker, Edwards, Miller, & Kaushal, 2012; M. Goldstein, 2010; NYeC, 2012; Williams et al., 2012). Additionally, there are no standardized processes that guide informed consent in general (Rothwell et al., 2014). This is concerning for all patients but particularly for PLWH, given the complex situations that PLWH experience while navigating the healthcare system, such as discrimination, fear, and a lack of trust for providers (Bradford, Coleman, & Cunningham, 2007; Loomis, Stiles, & Porter, 2013).

New York State (NYS) operates under the model of written, affirmative, patient consent as a prerequisite to electronically share PHI. Given the potential for PLWH to benefit from the outcomes of HIE, it is important to explore which factors affect an individual's decision to consent to HIE and the manner in which the sociotechnical context for HIE consent can be improved.

Problem Statement

Approximately 314 million persons reside in the United States, and of that, 1.2 million persons are living with HIV (Zeglin & Stein, 2015). In New York City, approximately 134, 000 are PLWH. New York State had the fourth highest number of HIV diagnoses, surpassing the total aggregated diagnoses rates in Maryland, New Jersey, and Pennsylvania (CDC, 2014). Locally, New York City (NYC) has seen a 28.4% increase in HIV diagnoses since 2001, and there are 113,319 diagnosed persons as of December 2011 (CDC, 2014).

African Americans and Latinos accounted for 78% of the new 2011 diagnoses in NYC (Wilson et al., 2014). The race and ethnicity of those burdened by HIV in NYC may present particular challenges to HIE. These include historical distrust of healthcare providers and inadequate utilization of healthcare (Halbert, Armstrong, Gandy, & Shaker, 2006; Hammond, 2010). Persons living with HIV are diverse in race, ethnicity, culture and socioeconomic status in addition to their care needs. As a result, healthcare providers are challenged to meet the unique and multifaceted needs of PLWH.

To address some of the health-related needs of the diverse PLWH, comprehensive care is a necessity. Comprehensive care is the result of excellent communication between PLWH and their healthcare providers, who have the greatest leverage in assisting PLWH to modify, change, and adapt to healthier behaviors (Grimley, Bachmann, Jenckes, & Erbelding, 2007). Moreover, sharing PHI among healthcare providers can increase the quality of the outcome of care for PLWH (Furukawa et al., 2014; J. E. Richardson, Abramson, & Kaushal, 2012). To date, the relationship between the characteristics of PLWH, the sociotechnical context in which consent is obtained, and the decision to electronically share PHI remains unclear.

To address the challenges related to HIE for PLWH in NYC, it is important to understand the sociocultural context of HIE including personal characteristics of PLWH that influence their decision to consent to HIE and to design innovative solutions to support PLWH decision making related to HIE consent.

Purpose

Toward the long-term goal of improving care and patient outcomes for PLWH through HIE, the purposes of this dissertation were to: (1) describe the sociotechnical context of HIE consent in one HIV clinic and (2) to design an electronic consent tool (eConsent) through user-centered design methods and pilot test the eConsent in a sample of PLWH. These purposes were achieved through Phases 1 and 2 of the dissertation research, respectively.

Theoretical Model

The Eight Dimension Sociotechnical Model

Phase 1 of this dissertation research was guided by the Eight Dimension Sociotechnical Model (Sittig & Singh, 2010). The choice to utilize a sociotechnical approach was premised on the interrelationship between technology and social aspects that are involved in contributing to the formation of new technical knowledge within the context of designing complex health information technology (HIT) -related interventions (Sittig & Singh, 2010). Specifically, these eight domains are as follows: (1) hardware and software, (2) clinical content, (3) human-computer interaction, (4) people, (5) workflow and communication, (6) internal organizational policies, procedures, and culture, (7) external rules, regulations and pressures, and (8) system measurement and monitoring (Table 1).

Table 1

Description of the eight sociotechnical dimensions (Sittig & Singh, 2010).

Dimension	**Definition**
Hardware and software	The hardware and software required to run, store and retrieve both structured and unstructured data
Clinical content	All data elements that are stored in the system
Human-computer interface	The users interaction with the system
People	Key stakeholders involved in all aspects of utilization of HIT
Workflow and communication	Two-way collaboration with the key stakeholders to accomplish streamlined care
Organizational policies and procedures	Workflow, communication, hardware and software that facilitates the organization’s guidelines
External rules, regulations, and pressures	Facilitators or barriers that influence HIT initiatives in the clinical setting
System measurement and monitoring	The availability, functionality, effectiveness and outcomes of HIT in the clinical setting

Cognitive Theory of Multimedia Learning

The Cognitive Theory of Multimedia Learning (Mayer, 1997) informed the design of the eConsent. The theory is premised on the notion that individuals learn from words and pictures that can be represented in illustrations, diagrams, animations and include reading, watching and listening. Three assumptions (dual-channel, limited-capacity, and active processing) assert that learning is processed via separate communicatory channels in the brain (Mayer, 1997). Dual-channel processing facilitates visual and verbal processing, and limited-capacity inhibits individuals from consuming large amount of information in order to prevent cognitive overload (Miller, 1956). Active learning is facilitated by presenting new information in small sections to improve comprehension and build upon previous knowledge (Rothwell et al., 2014). Finally, meaningful learning is activated when the appropriate cognitive processes are engaged by integrating the principles of multimedia learning into cognitive theory (Mayer, 1997).

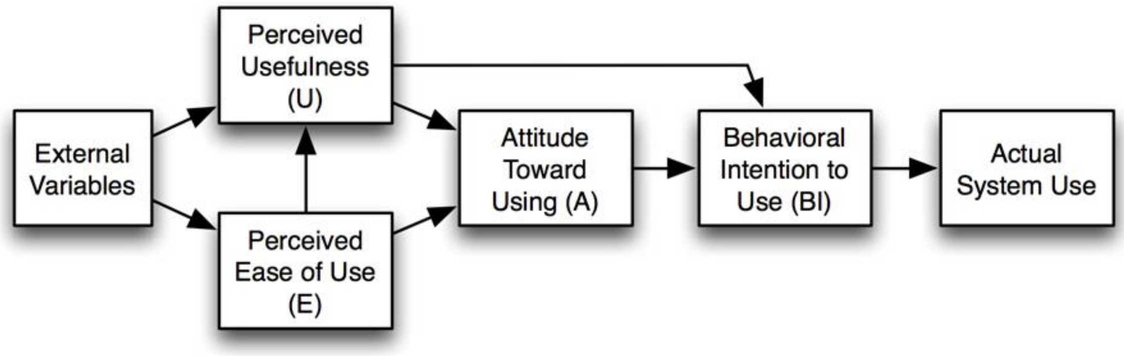
Twelve principle of multimedia learning guide the design and organization of engaging individual presentations (Mayer, 1997; Mayer & Moreno, 2002). The principles are as follows: (1) coherence, (2) signaling, (3) redundancy, (4) spatial contiguity, (5) temporal contiguity, (6) segmenting, (7) pre-training, (8) modality, (9) multimedia, (10) personalization, (11) voice, and (12) image (Mayer, 1997; Mayer & Moreno, 2002). The principles coherence, signaling, multimedia, and personalization specifically informed the design of the HIE eConsent. This was done using words and pictures that were illustrated using animations, which were read by the study participants.

The coherence principle refers to the omission of extraneous words and information (Mayer, 2009). Signaling utilizes cues to highlight information that inform the user of the organization of the material (Mayer, 2009). Multimedia utilizes two mediums for learning, such as pictures and text, instead of relying on solely one method (Mayer, 2009). Personalization presents words in an informal, lay style reducing the complexity of formally worded information (Mayer, 2009).

Technology Acceptance Model

The Technology Acceptance Model (TAM) (Davis Jr, 1986) informed the Phase 2 pilot test of the eConsent. TAM (Figure 1) was an appropriate model to achieve a better understanding of PLWH's acceptance of the integration of technology in facilitating HIE consent. According to Davis (1986), perceived usefulness is the extent of expected impact of system use on job performance, and perceived ease of use is the extent to which an individual believes that the system is free of cognitive or physical effort. In this study, perceived usefulness was identified as the participant's perception that eConsent was a more convenient facilitator of HIE consent than the paper consent. Perceived ease of use was identified as the participant's ability to navigate the eConsent intuitively and effortlessly. These were measured with a 4-question, 5-point Likert scale questionnaire. The constructs of behavioral intention to use and actual system usage were not measured in this study as the utilization of this model was focused on user eConsent preference and eConsent ease of use.

Figure 1. The Technology Acceptance Model (Davis Jr, 1986).



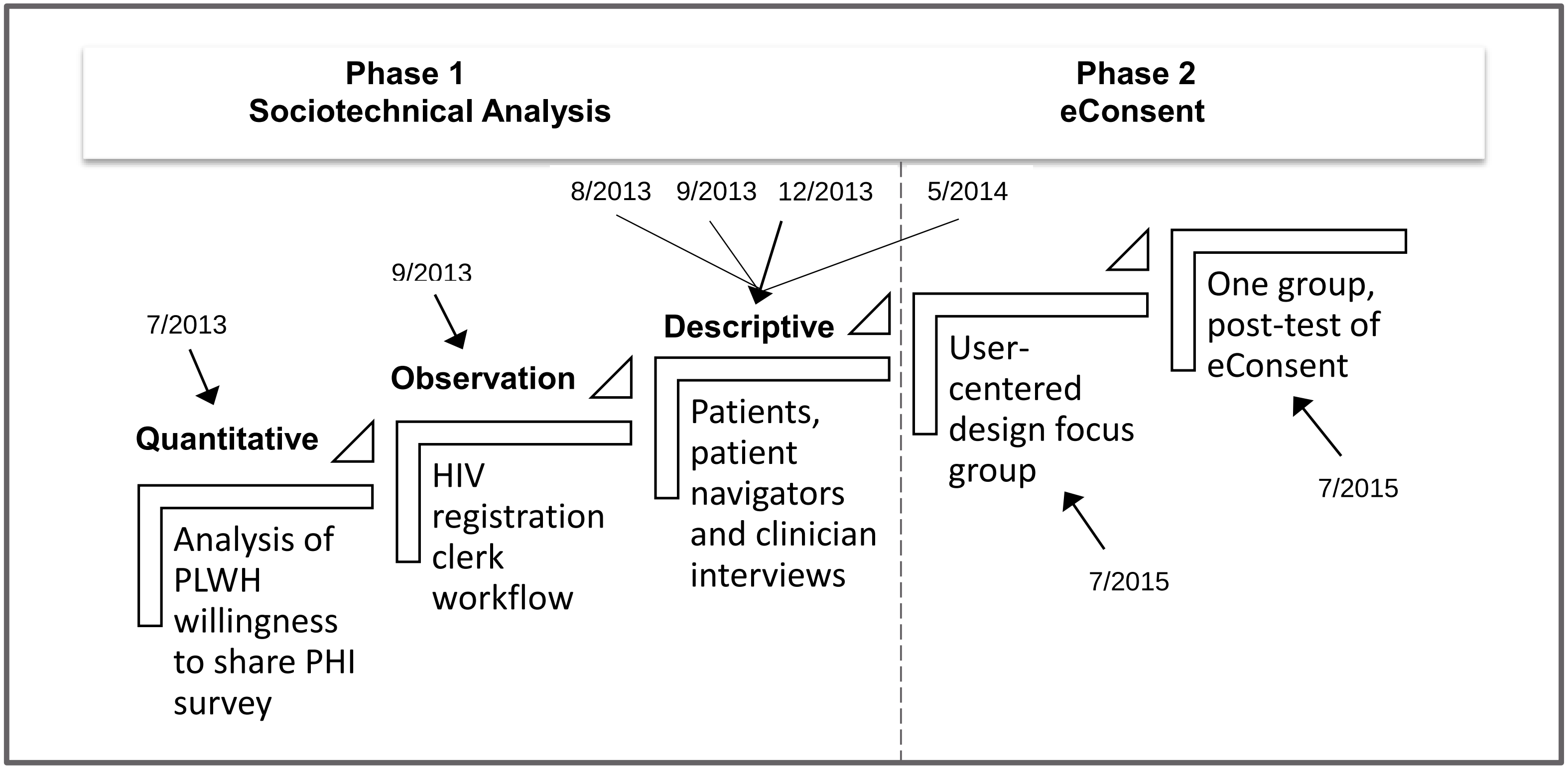
Dissertation Overview

The research is organized into two phases (Figure 2) comprising three specific aims:

1. To explore the sociotechnical context of obtaining HIE consent in an HIV clinic.
2. To apply a user-centric approach to design an HIE eConsent for PLWH at a HIV clinic.
3. To examine PLWH perceptions of the usefulness and ease of use of an eConsent for HIE, the preferences for eConsent as compared to paper consent, and comprehension of HIE concepts.

The methods for each aim are summarized in Table 2. Terms are defined in Table 3.

Figure 2. Illustration of research process for this HIE consent study.



*Dates indicate points of data collection

Table 2

Summary of Study Methods.

	Design	Sample	Methods
Phase 1 Sociotechnical Analysis	Secondary Data Analysis	(N= 291) HIV clinic patients	Logistic regression using the Bonferroni correction
	Descriptive Observational	(n = 4) Registration Clerks	Workflow observations and semi-structured interviews
	Qualitative	(n = 19) 12 patients 3 patient navigators 4 clinicians	Semi-structured interviews and focus groups
Phase 2 eConsent Design and Pilot Study	Mixed Methods	(N = 25) Clinic patients n=5 an icon focus group n=20 one group, post-test design with comprehension testing	Focus group, post-test, semi-structured interviews

Conclusion

African Americans and Latinos are disproportionately affected by the HIV epidemic. The prevalence of multiple comorbidities and the current state of fragmented healthcare remain critical dilemmas for this population. Health information exchange has the potential to decrease healthcare fragmentation through sharing of PHI among healthcare providers. However, little is known about the factors that influence PLWH to share PHI or the sociotechnical context of HIE consent in HIV. Such information is needed as the foundation for innovative solutions to facilitate HIE consent.

Table 3

Definition of terms.

Term	**Definition**
Affirmative Consent:	Written, signed consent that is required by an individual in order to provide a service or participate in research.
Apple Research Kit [Application 'App']	Open, customizable software for medical and health research use.
Cognitive Theory of Multimedia Learning	Individuals learn best from words and pictures.
Continuity of Care	Clinician and patient dual involvement and management in patient's health to deliver quality care.
Care Continuum or Cascade	A series of steps necessary for PLWH to achieve viral load suppression.
Comprehension	The ability to understand and process written material.
Electronic Health Record (EHR)	An electronic version of a patient's medical record. Synonymous with EMR.
Health Information Exchange (HIE)	The secure, electronic sharing of patient health information among multiple healthcare providers and facilities.
Health Information Technology (HIT)	Assorted technologies used for storing, analyzing, and sharing health information electronically.
Health Insurance Portability and Accountability Act (HIPAA)	A series of safeguards that protect personally identifiable health information.
Informed Consent	The act of granting permission with a complete understanding of the risks and benefits.
Meaningful Use (MU)	A set of standards for increasing the usage and functionalities of EHRs to improve healthcare.
Eight Dimension Sociotechnical Model	Multi-interrelated, fluid model with Eight Dimensions for exploring the utility of HIT interventions.
Technology Acceptance Model	Explores user adoption behaviors towards technology.
User-centric Design	User-centric engagement and feedback during the design process.
Visualization	Creative graphics used to convey information.

Chapter Two

Review of the literature

The factors that influence PLWH’s decision to consent and share all PHI electronically via HIE remains unclear. The purpose of this chapter is to provide a review of the literature regarding the context of HIE affirmative consent procedures in the HIV clinic environment. As background, literature related to: (1) technology in healthcare, (2) health information exchange, (3) unstandardized HIE consent procedures, (4) HIE utilization in NYS, (5) national HIV/AIDS strategy, and (6) literacy and informed consent is addressed in this chapter.

A comprehensive literature search strategy was employed to identify all appropriate literature utilizing the following online databases: MEDLINE ®, EMBASE®, CINAHL®, Web of Science® and Google Scholar. Selections of the aforementioned databases ensured coverage of international, biomedical, nursing/allied health, life science, research and scholarly literature. Moreover, to capture all relevant literature, hand searches were performed, and literature was identified from secondary sources, such as reference lists and online white papers.

Health information exchange is an evolving concept in healthcare, and evidence in the literature exists reporting that various forms of health information technology have been used for over a decade. Since technology utilization is constantly changing, it was worthwhile to assess literature dating back 20 years. The Medical Subject Heading (MeSH) browser was used to explore the following terms: health information exchange, HIV, informed consent, meaningful use, consumer health information, health literacy, and informatics. In order meet inclusion criteria, articles had to be as follows: (1) written in English, (2) focused on HIE, (3) included PLWH as the primary sample, (4) mentioned HIE, PLWH or HIV in the article title, (5) peer review journals article, white paper, and/or a government website that was specific to HIE.

Exclusion criteria included: (1) articles not published in English, (2) abstract only publications, and (3) articles that focused solely on HIT and not HIE. No studies were located that specifically addressed eConsent to HIE for PLWH. Meeting the diverse needs of PLWH in regards to HIE informed consent is understudied, and the researcher seeks to address this knowledge gap.

Technology in healthcare

Health information technology (HIT) has had a significant impact on the way patient data is accessed, utilized, and stored. It provides efficient ways for healthcare providers to securely document patient data, prescribe medications, and view summative clinical data. Health information technology includes applications such as electronic health records (EHRs), personal health records (PHRs), and electronic prescribing (E-prescribing) (Street, Gold, & Manning, 2013).

Studies have documented that utilization of these technologies has resulted in decreased duplicate testing, safer and more efficient prescribing and dispensing practices (Wu et al., 2006), and well-organized, up-to-date aggregated patient data. For over a decade, the utilization of HIT remains a continual national priority (Furukawa et al., 2014; W. C. Richardson et al., 2001) with the expectation of improved quality care, fiscal efficiency, and better patient outcomes. Health information exchange is facilitated by HIT and has the potential to impact PLWH. This study’s main focus is HIE as a mechanism for improving patient outcomes and efficient coordination of care. HIE is an important area of application for PLWH because of the significance of supporting the continuum of care (Figure 3).

Figure 3. Illustration of how HIE supports the continuum of care.

Health Information Exchange

Health information exchange is the secure, electronic transfer and/or accessibility of a patient’s medical records from one healthcare provider to another (Patel et al., 2012). It is a vital element for the healthcare environment, and when fully leveraged, it can improve patient safety, healthcare quality, care continuity, and surveillance reporting (Williams et al., 2012). Examples of this are as follows: (1) improving safety—knowledge of a patient’s current medication and allergy status, (2) quality of care—decreased fragmented care through informative and efficient viewing of patient encounters, (3) care continuity—patient treatment and care at facilities other than their primary care center that is appropriate and in sequence from previous encounters, and (4) surveillance reporting—electronic access to data on new occurrences of diseases or other events that require reporting (Kierkegaard, Kaushal, & Vest, 2014).

The goal of HIE is the provision of coordinated and efficient care, where patient health information is accessible in a protected and secure manner to clinicians in any healthcare environment (Williams et al., 2012). Health information exchange is a facilitator of care coordination by providing a real-time record of patient encounters, thus decreasing errors in care due to inaccessibility of pertinent information, such as allergies and prescribed medications (DesRoches et al., 2008; Kaelber & Bates, 2007; Middleton, Hammond, Brennan, & Cooper, 2005; Wu et al., 2006). In emergency situations, it can potentially save lives (DesRoches et al., 2008; Kaelber & Bates, 2007; Middleton et al., 2005). An example would be “breaking the glass,” an action taken by a healthcare provider to access patient medical records electronically in a situation where the individual is incapacitated (Kim, Joseph, & Ohno-Machado, 2015).

The Health Resources and Service Administration (HRSA) HIV/AIDS Bureau (HAB) has defined a continuum of care as an “integrated service network that guides and tracks clients through a comprehensive array of clinical, mental, and social services in order to maximize access and outcomes” (Cheeks, 2012). This definition suggests that a technology-enabled continuum of care, such as one supported by the HIE mechanism, has the potential to improve health outcomes and quality of care for PLWH.

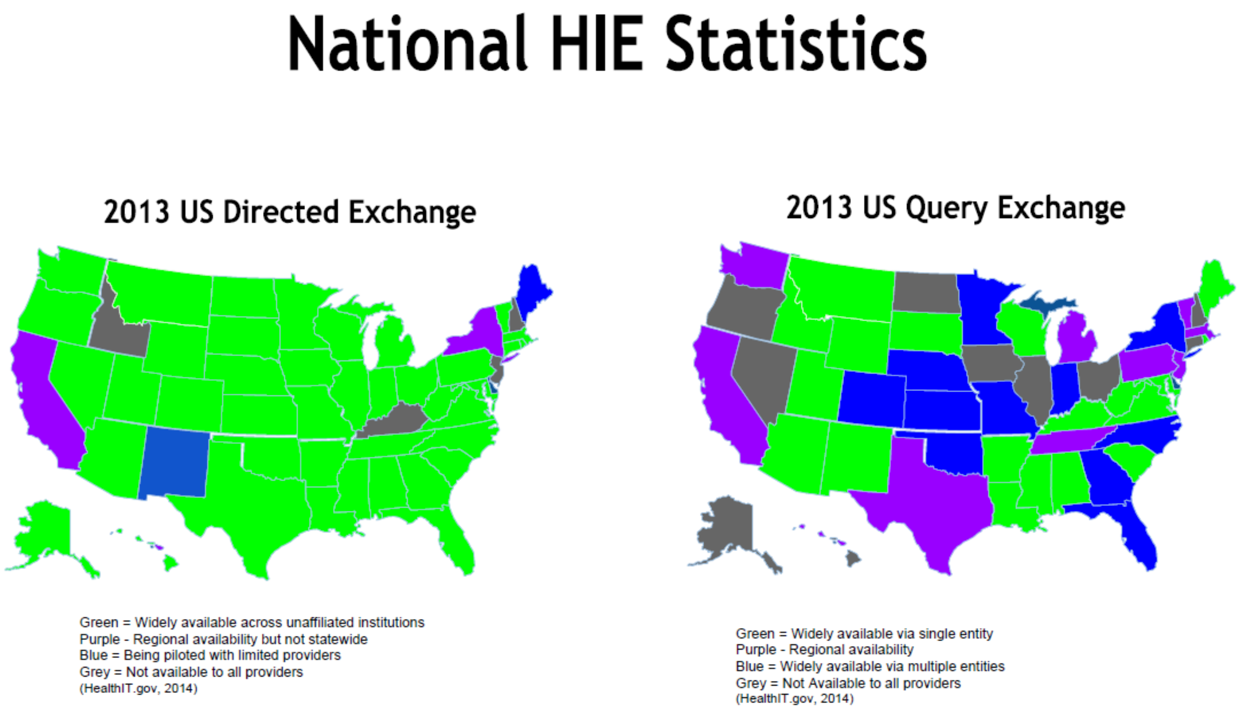
Benefits of HIE

Identifying PLWH that are out-of-care and sending electronic alerts to their healthcare providers are an innovative usage of HIE. For example, the Louisiana Public Health Information Exchange (LaPHIE) was created with the aim of engaging, reengaging, and retaining PLWH who are out-of-care and linking them back in to care (Magnus et al., 2012). Herwehe and colleagues suggested that linking public health data with electronic medical records to provide clinical decision support was integral in improving patient health status (Herwehe et al., 2012). These studies demonstrated that LaPHIE improved patient utilization of HIV care, and it also impacted patient engagement, which was demonstrated by undetectable HIV serology. Hence, the ability to positively impact the health outcomes of PLWH by using technology-enabled care coordination is an area of high priority.

Mechanisms of HIE

Currently every state employs a form of HIE, whether it is a directed or query-based mechanism (Figure 4), which are the two most common mechanisms (Williams et al., 2012). Directed exchange securely transmits data to a specific person, similar to a secure email message. Query-based exchange is the process of securely looking up patient information by using patient identifiers (name, medical record number and/or date of birth) and then having the information electronically "pulled" to the location of the inquiring provider (Williams et al., 2012).

Figure 4. Illustration of national directed and query-based HIE exchange.



Federal drivers of HIE

Established in 2004, the Office of the National Coordinator for Health Information Technology (ONC) was responsible for the implementation and widespread usage of HIT in the healthcare setting (Kuperman, 2011; Williams et al., 2012). Under the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, specific eligible healthcare providers had to meet certain usage criteria of their EHR systems in order to qualify for incentives, as determined by Centers for Medicare & Medicaid Services (CMS) (Williams et al., 2012). This large-scale investment was intended to increase the usage of EHRs, the sharing of data from provider-to-provider, and the usage of information for research and quality outcome metrics (DesRoches et al., 2008). Healthcare providers were mandated to use certified EHRs that had the capability and functionality to securely enter, access, transfer, and store patient data (Blumenthal & Tavenner, 2010). This incentive program was intended to facilitate the "meaningful use" of EHRs in ways that improve the care of patients by meeting pre-specified core objectives.

Stage 1 core objectives of meaningful use included electronic capture of patient data and provision of patients with electronic copies of their health information (Blumenthal & Tavenner, 2010). This included computerized physician order entry, clinical decision support, e-prescribing, and reporting of surveillance data (Blumenthal & Tavenner, 2010; Kuperman & McGowan, 2013). In an effort to improve care coordination, stage 2 meaningful use foci were to electronically exchange clinical data with patients and providers via HIE. The core objectives included transmission of immunization data to public health registries, secure electronic messaging between providers and patients, and patients' accessibility to their own health records electronically through a PHR portal (Blumenthal & Tavenner, 2010). Recommendations for the final stage of meaningful use (stage 3) are improved patient outcomes through advanced HIE usage, such as quality reporting metrics and widespread interoperability.

An important component of meaningful use core objectives is interoperability. Interoperability is the ability of unaffiliated EHR systems to communicate and link data electronically in a readable format for providers (Kern, Barron, Abramson, Patel, & Kaushal, 2009). This has the potential to reduce healthcare costs and increase efficiency, quality, safety, and care coordination (Campion Jr, Vest, Kern, Kaushal, & investigators, 2014; Williams et al., 2012). New provider payment mechanisms, reimbursement, and quality reporting indicators necessitate interoperability (Williams et al., 2012).

Non-standardized HIE Consent Procedures

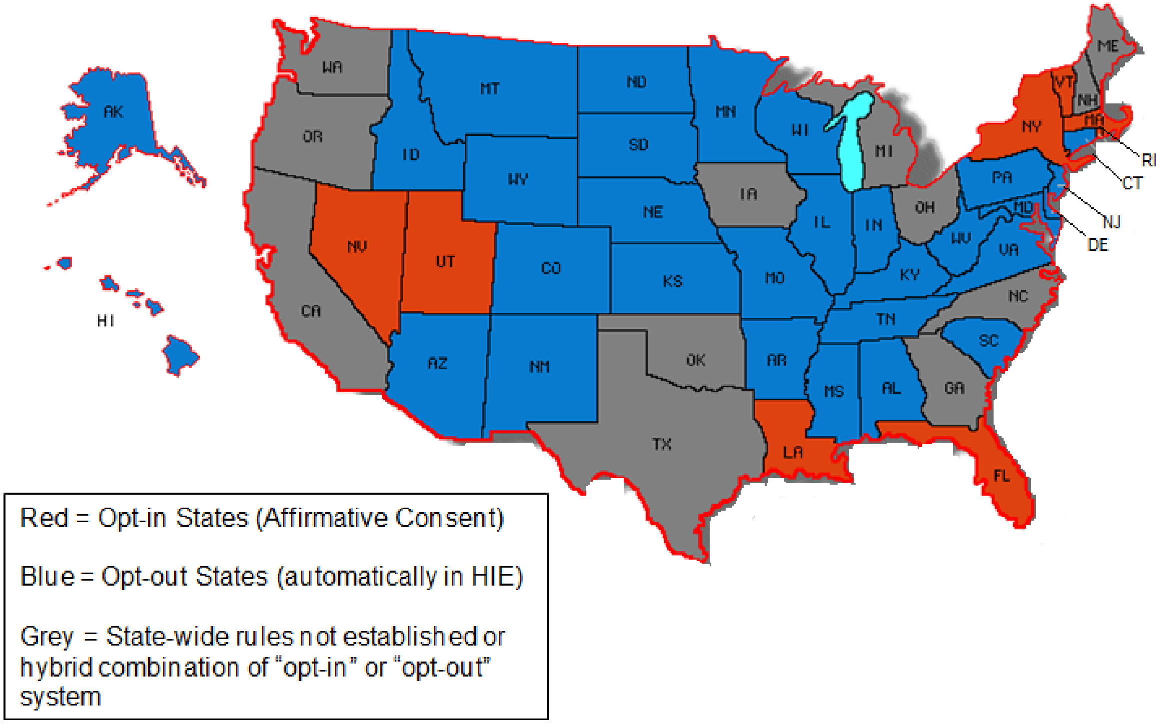
In the U.S., there are no standardized processes by which the components of HIE informed consent are presented, discussed and obtained (Rothwell et al., 2014). This includes PLWH's decision to consent to electronically share their medical records with their healthcare providers via HIE. According to the state in which an individual resides, some are able to control what information they are willing to share electronically. Although every state and territory utilizes HIE, a lack of standardized consent models (i.e., "opt-in" and "opt-out") restricts various levels of PHI that is allowed to be shared. Figure 5 illustrates the non-standardized and fragmented consent models in the U.S. Currently, there are five core consent models: (1) no-consent, (2) opt-out, (3) opt-out with exceptions, (4) opt-in (affirmative), (5) and opt-in with restriction (Gray, 2011).

In the no-consent model, a patient's PHI is automatically entered into the HIE. States such as Indiana utilize this model and have benefited from a robust statewide HIE infrastructure.

A downfall of such a consent model is the lack of control patients have in regard to the data that is shared electronically since they are automatically included in the exchange. However, a patient may formally deny access to having all their information electronically shared (Gray, 2011).

The “opt-out” model assumes patient participation in the HIE until the patient formally opts out. A patient may limit who can view his or her PHI by residing in a state that abides by an opt-out with exceptions model. In an “opt-in" or affirmative consent model, a patient must affirm or sign a consent in order to have PHI accessed via HIE. A hybrid form of “opt-in” is the opt-in with restriction model; Rhode Island endorses this model. Patients may selectively limit who has access to their health records and the data elements that are shared (Gray, 2011).

Figure 5. Illustration of unstandardized national HIE consent models.



In light of the many options that healthcare consumers have regarding the model of consent offered in their state, the HIE’s value can only be demonstrated by the amount of data or persons who participate in the exchange (Bass, 2011). Internationally, similar opt-in consent modalities take place in France, Belgium, Spain, and elsewhere (Schwartze et al., 2013). In contrast, more than two-thirds of HIE processes occur with no-consent in Austria (Schwartze et al., 2013). In a German study, HIE opt-in consent was obtained via paper or electronically by a medical assistant (Schwartze et al., 2013).

New York State HIE Consent Procedure

Even though every state may utilize HIE, the consent process for participation varies state to state (M. M. Goldstein, 2010), as does the amount of information one can consent to share. At this time, there is not a national standard for HIE consent or the process of obtaining consent (Ancker et al., 2012; M. Goldstein, 2010; NYeC, 2012; Williams et al., 2012). In contrast to "opt-out" states, the NYS consent model mandates written HIE patient consent. Without affirmative consent in NYS and other "opt-in" states, information is not able to be shared electronically. However in some "opt-in" states, individuals have the option of allowing access but with limitations, such as behavioral health and substance abuse history (Gray, 2011). In emergency situations when patient data is needed to be accessible electronically, a physician may "break the glass" and access the patient's PHI in order gather necessary information to safely provide emergency treatment and care (Kim et al., 2015; NYeC, 2012).

New York State Regional Health Information Organization

New York State maintains 8 regional health information organizations (RHIOs) to act as network hubs for storing and sharing electronic patient medical data (NYeC, 2012). Moreover, it facilitates interoperability, data security, and compliance via a Statewide Collaboration Process that is comprised of the New York eHealth Collaborative and the NYS Department of Health (NYeC, 2012). As of recent, 84% of the state is able to access and transfer patient medical data throughout the region. Thus, connecting numerous stakeholders, such as healthcare organizations, providers, laboratories, and pharmacies, is beneficial and efficacious for improving care delivery (Kern et al., 2009).

Healthix

Healthix is the RHIO that provides HIE for approximately 10 million consented patients residing in the downstate area of NY (Garg et al., 2014). This includes Manhattan, the Bronx, Brooklyn, Queens, Staten Island, and Long Island (Healthix, 2015). As the largest RHIO in NYS, Healthix comprises over 500 locations and more than 150 organizations that utilize this data to provide safer treatment and better decision making on behalf of patients'(Garg et al., 2014). Healthix is focused on providing quality, efficiency, and safety (Healthix, 2015). Quality is facilitated through improved coordination of care where healthcare providers are able to access real-time data on patient encounters at both affiliated and non-affiliated clinical sites that participant in the RHIO. Efficiency decreases duplication of diagnostic imaging and laboratory testing, and it makes results readily accessible without having to contact other facilities or providers for results. Safe care is provided when the healthcare provider can access a patient's allergy status, health history, and medical treatment history. This reduces medication errors and misdiagnosis and provides insights to providers on how to better optimize care. Healthix is Health Insurance Portability and Accountability Act (HIPAA) compliant, as all information is protected by federal and state privacy and confidentiality laws (Healthix, 2015). Information is collected, transferred, and shared electronically and securely with hospitals, nursing homes, pharmacies, NYS Medicaid medical home programs, and health insurers (Healthix, 2015).

Importance of HIE for PLWH

Prior research conducted as part of this dissertation has suggested that one of the most pertinent reasons patients decline to consent to share all of their information electronically is misinformation or misunderstanding about the definition and implications of HIE (Ramos & Bakken, 2013). Personal factors (e.g., level of comprehension or literacy) may be barriers to HIE consent. Patel and colleagues proposed the creation of high-quality, understandable, culturally responsive materials to illustrate the value of PHR/HIE adoption for healthcare consumers (Patel et al., 2011). The question regarding who is the appropriate person/s to obtain HIE consent remains unclear. At a provider site in Nebraska, patients learn about the HIE consent from unspecified staff and sometimes inadvertently "opt-out" because they were misinformed (Bass, 2011). Thus, "opt-in" models carry the administrative burden of deciding who will obtain the consent, in which format will the consent be delivered (paper or electronic format), and whether primary care providers should obtain consent for their own patients (Gray, 2011).

For PLWH, electronic sharing may be advantageous for improved care and health outcomes. For instance, HIE decreases healthcare silos through electronic sharing between primary care providers, specialists, pharmacies, hospitals and laboratories where the patient is the primary focus of care. Multiple studies have explored patients' attitudes with sharing their PHI electronically, and the results have varied widely. Reasons for not wanting to share PHI were fear or privacy/confidentiality of their data, fraud/identity theft, and discrimination (Dimitropoulos, Patel, Scheffler & Posnack, 2011). Usage by third parties for research, governmental, or insurance purposes was viewed negatively (Whiddett, Hunter, Engelbrecht & Handy, 2005). Moreover, some studies with high minority populations suggested that patients who lacked information or knowledge about HIE were less likely to participate (Patel et al., 2011; Whiddett et al., 2005). Prior knowledge or experiences may impact decision making for PLWH, such as literacy level, trust in healthcare providers, fear of discrimination based on serostatus, and perceived stigma (Bradford et al., 2007; Loomis et al., 2013)

Additional studies have identified that trust in the medical team and quality patient/provider visit time influenced patient attitudes to want to share their personal information (Teixeira, Gordon, Camhi & Bakken, 2011; Maiorana et al., 2012; Patel et al., 2011). A continuity of care document (CCD), *My Health Profile,* was implemented for PLWH in a NYC HIV clinic. This study identified that patient usage of a CCD is facilitated by addressing privacy/security concerns and computer skills to support care coordination and better healthcare (Gordon et al., 2012). Dhopeshwarkar et al. (2012), found that men had a more positive view of sharing their PHI without consenting first if they were comfortable using a secured internet connection. Patel et al. 2011, also found that prior internet usage and comfort impacted PHR usage. A study in South Korea noted that a large sample of women indicated a preference for consenting to participate in HIE (Park et al., 2013). Moreover, the respondents believed that HIE was beneficial because it expedited their care with providers and also resulted in the patients not having to carry their paper medical records to all of their healthcare visits (Park et al., 2013).

Because technology is becoming so predominate in primary care areas, patients are becoming more accustomed to their health data being viewed electronically (Maiorana et al., 2012). When fully leveraged, engaging patients by providing trust, information, and reassurance of security/privacy measures will facilitate increased responsiveness to HIE. However, little is known about the perceptions of PLWH when deciding to electronically share all of their PHI with healthcare providers. Additionally, because there are currently no standardized processes of obtaining HIE consent, little is known about how to better facilitate HIE consent process for PLWH.

Disproportionate HIV rates

In NYS, HIV diagnoses ranked fifth in the nation when compared nationally (CDC, 2012a; HIV/AIDS, 2011; Kern et al., 2009). From the 1990's to the present, approximately 50,000 new HIV infections per year have been diagnosed in the U.S. (CDC, 2012a; Hall et al., 2008; Vest, 2012). Persons of minority racial/ethnic origins and those who identify as gay or bisexual are disproportionately affected (Gardner, McLees, Steiner, del Rio, & Burman, 2011; Hixson, Omer, Del Rio, & Frew, 2011; Nguyen et al., 2008). Of all newly diagnosed infections, 63% of the population are gay and bisexual men, 25% are heterosexuals, and 8% are injection drug users. When compared with females, males and African Americans bear the highest HIV diagnosis burden, with greater than 515,000 residing in the U.S. (Odlum et al., 2012).

Regionally, African Americans have the highest rates of diagnosis in the Northeast, Midwest, and South, with Latinos placing second. The HIV burden for the Latino population continues to rise. Latinos comprise 16% of the U.S. population, and yet there are approximately 220,000 Latinos living with HIV (CDC, 2012c). New York, Miami, and Los Angeles have the highest new diagnosis rates and are also areas with high Latino populations (Darmon, Sauvant, Staccini, & Letrilliart, 2014). Gay and bisexual men account for greater than half of new HIV cases for European Americans and African Americans, respectively (Aghaizu, Brown, Nardone, Gill, & Delpech, 2013). Unfortunately and despite advances in HIV research, medications, and treatment options, HIV continues to be problematic, especially in ethnic and sexual minority populations (Remien et al., 2015). In NYC, approximately 73% of those diagnosed with HIV and linked into care were retained in HIV services.

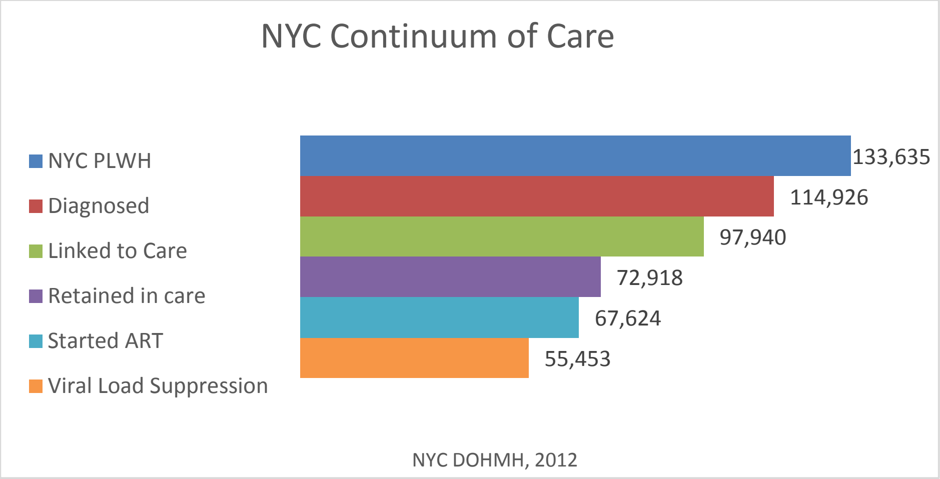
New York City HIV Cascade

The HIV Cascade (Yehia et al., 2015) represents a care continuum for diagnosis, linkage, and retention (Figure 6). The ultimate goal of the stages is viral load suppression. A critical first step in the continuum of care is diagnosis, since approximately 168,000 HIV positive persons remain unaware of their serostatus (CDC, 2012c; Hall et al., 2015). Early diagnosis can potentially change transmission behaviors and reduce transmission rates (Gardner et al., 2011; Hall et al., 2015).

Linkage to care has been associated with a reduction in opportunistic illness and AIDS diagnoses. However, a lifelong commitment to engagement in care is necessary (Gardner et al., 2011), thus reducing morbidity and mortality through retention (Hall et al., 2015; Remien et al., 2015), and yet almost 50% of PLWH are lost to follow-up (Arici et al., 2002; Coleman et al., 2007; Gardner et al., 2011; Hill et al., 2010; Mocroft et al., 2008).

The precursor to viral load suppression, defined as less than 50 HIV copies/ml, is the initiation of antiretroviral therapy (Gardner et al., 2011). Viral load suppression enables PLWH to have improved health quality, stronger immune systems, and incidence reduction of new HIV transmission (Gardner et al., 2011; Hall et al., 2015). Therefore, enabling the care continuum through HIE has the potential to inform both individuals and communities. It facilitates effective coordination of care though follow-up and retention to help achieve viral load suppression of PLWH. An example of this would be a newly diagnosed PLWH getting linked into HIV care, being started on HIV medications, and then achieving viral load suppression. Without HIE as an enabler to the care continuum, PHI will continue to be fragmented, and linkage and retention in care will be difficult to achieve.

Figure 6. Illustration of the totals of PLWH in the context of the HIV Cascade.



National HIV/AIDS Strategy

On July 13th, 2010, *The National HIV/AIDS Strategy* was announced through the White House with the aims of reducing new HIV infections, improving the health outcomes and access to healthcare services, and reducing health disparities for PLWH (Millett et al., 2010; "The National HIV/AIDS Strategy for the United States and the National HIV/AIDS Strategy: Federal Implementation Plan," 2010). The strategy's goal for increasing access to care and improving health outcomes for people living with HIV is ongoing. One initiative from HRSA's Special Projects of National Significance (SPNS) seeks to support the engagement and retention of HIV positive Latinos through the creation, implementation, and evaluation of patient-centered interventions. It has been documented that both African Americans and Latinos face HIV health inequities because of little to no access to care services, cultural barriers, HIV stigma, low health literacy, and low self-efficacy. Hence, effective HIE can alleviate the many problems surrounding prevention, linkage, access and disproportionate HIV burden.

Literacy and Informed Consent

Literacy is an essential foundation for written, informed consent. Approximate 40 million persons living in the U.S. have below basic numeracy skills (Peters, Meilleur, & Tompkins, 2014), and approximately 80 million have low levels of health literacy (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011). Basic numeracy skills include identifying numbers and obtaining the sum of the numbers (Peters et al., 2014). Numeracy refers to the skills necessary to utilize quantitative information in a meaningful and informed way (Peters et al., 2014; Selden, Zorn, Ratzan, & Parker, 2000). Health literacy is the ability to process textual information in order to effectively leverage health information and health-related decisions (Berkman et al., 2011; Sentell & Braun, 2012).

Persons with deficient literacy and numeracy are not able to make connections about messages appropriately, thus being unable to interpret, process, and resolve information effectively. Based on the literature, it can be inferred that those living with HIV who are of low socioeconomic status are inclined to have low health literacy and numeracy skills (Osborn et al., 2011; Osborn, Paasche-Orlow, Davis, & Wolf, 2007). One innovation for closing this gap is to use electronic visualization as a tool to communicate messages in a more understandable and meaningful way, such as on a tablet. Visual aids have been used to inform people regarding health risks for an extended period of time (Fagerlin et al., 2007; Garcia-Retamero & Galesic, 2010; Garcia-Retamero, Okan, & Cokely, 2012; Stone et al., 2003; Zikmund-Fisher et al., 2008), yet little is understood about how electronic visual aids can better inform PLWH about HIE. To this extent, it was imperative to review what is currently known about incorporating multimedia into an unstandardized consent processes.

Multiple efforts are made by institutional reviews boards to ensure the safety and protection of study participants. Although informed consent for research and for HIE are not synonymous, the processes by which they are understood by the patient is relevant. However, the literature suggests that similar efforts are not concentrated on the actual process of discussing, obtaining, and ensuring comprehension of study procedures prior to participation (Rothwell et al., 2014). This has resulted in the lack of understanding the fundamental components of informed consent, such as: (1) study procedures, (2) participant rights, (3) risks/benefits, (4) privacy/confidentiality of obtained data, and (5) voluntary participation (Agre & Rapkin, 2003; DHHS, 2009; Flory & Emanuel, 2004; Henry et al., 2009; Palmer, Lanouette, & Jeste, 2011; Rothwell et al., 2014).

In a systematic review (Flory & Emanuel, 2004), researchers suggested that direct contact discussion with participants would be the most meaningful way to improve understanding during informed consent. In contrast, Palmer and colleagues contend that using multimedia in consents improved a participant’s comprehension (Palmer et al., 2011). A definitive answer remains unclear and warrants more exploration, particularly for populations living with HIV, which have varying levels of literacy and comprehension. As a vulnerable population, it is imperative to provide due diligence when discussing the elements of informed consent with PLWH, especially since most medical consent forms are written at the mid-college reading level (Doak, Doak, & Root, 1996; Meade & Howser, 1991). Strategies for effective visualization (animations, graphs, and electronic apps.) can potentially make information more cognitively accessible (EDUCAUSE, 2009). The full utilization of effective communication via multimedia cannot be fully realized without engaging members of the community for which the intervention was intended (Alper, 2015). A patient-centric approach is needed to respond to the variety of literacy and comprehension needs that exist in regards to HIE and the HIE consent process. Patient centeredness is defined as the provision of individualistic, responsive care where clinical decisions are driven by patient values (America, 2001; Krumholz, 2010). Because PLWH come from diverse backgrounds and their decision-making is based on multiple factors, the concepts of patient centeredness and patient-centric approaches may be instrumental in addressing how to better facilitate an informatics-based solution to reduce the barriers to HIE consent for PLWH.

Conclusion

The review of the literature suggests that HIV care is an important area for application of HIE because of the significance of supporting the continuum of care. Opt-in consent approaches for HIE such as that in NYS are challenging for multiple reasons including personal characteristics, such as level of health literacy and numeracy. Little is known about the general factors that influence HIE consent for PLWH in particular. The existing literature documents the need to further study the facilitators and barriers for HIE consent for PLWH and to develop innovative solutions to reduce the barriers to HIE consent, thus providing the motivation for the two dissertation studies. The first study applies a sociotechnical analytical approach to describe the facilitators and barriers to HIE consent within the context of one HIV clinic. The data collected was used to discover potential points of intervention and to select a target for Phase 2. The second study focused on the creation and pilot testing of an electronic consent (eConsent) for HIE.

Chapter Three

Sociotechnical Analysis of Health Information Exchange Consent Processes in an HIV Clinic

Introduction

In the U.S., there are approximately 314 million persons residing (NCfHS, 2014). Of that number, 1.2 million are living with HIV (CDC, 2013). The diversity in race, ethnicity, culture and socioeconomic status suggest that there is no single model of care that is suitable for all persons. Every day, healthcare providers are challenged in meeting the multifaceted needs of our diverse society. For instance, the literature has reported that PLWH encounter stigma and discrimination at the workplace, within their communities, and unfortunately in the healthcare arena (Land & Linsk, 2013; Stangl, Lloyd, Brady, Holland, & Baral, 2013). As a result, stigma, fear, and discrimination are three factors that have directly affected PLWH and the trust they have in their healthcare providers (Land & Linsk, 2013) when compared to non-PLWH (Whetten, Reif, Whetten, & Murphy-McMillan, 2008). This may be a reason why PLWH are not willing to electronically share all of their PHI using HIE (Bradford et al., 2007; Dimitropoulos, Patel, Scheffler, & Posnack, 2011; Loomis et al., 2013).

Health information exchange is the secure, electronic transfer and/or accessibility of a patient's medical records from one healthcare provider to another (Patel et al., 2012). It is important for PLWH because it facilitates care coordination by providing a real-time record of patient encounters, thus decreasing errors in care due to inaccessibility of pertinent information, such as allergies and prescribed medications (DesRoches et al., 2008; Hillestad et al., 2005; Kaelber & Bates, 2007; Middleton et al., 2005; Teixeira, Gordon, Camhi, & Bakken, 2011; Wu et al., 2006). In emergency situations, such as incapacitation, a medical provider's ability to access pertinent patient medical data can potentially save lives (DesRoches et al., 2008; Hillestad et al., 2005; Kaelber & Bates, 2007; Middleton et al., 2005; Teixeira et al., 2011; Wu et al., 2006).

Latinos and African Americans continue to be disproportionality affected by HIV (CDC, 2012b), and issues of perceived HIV stigma, discrimination, lack of English proficiency, and inadequate healthcare coverage are all antecedents to an individual's unwillingness to share their PHI electronically (Derose, Escarce, & Lurie, 2007; Teixeira et al., 2011; Whiddett, Hunter, Engelbrecht, & Handy, 2006). In the literature, healthcare provider distrust has been linked to non-adherence with medical care, low satisfaction with healthcare services, and poorer health outcomes when compared to non-PLWH (Land & Linsk, 2013). These issues may contribute to PLWH's decision to consent to HIE. Every state and territory utilizes a form of HIE, but varying unstandardized HIE consent models and fragmented information silos (Bass, 2011) continue to act as barriers to information sharing.

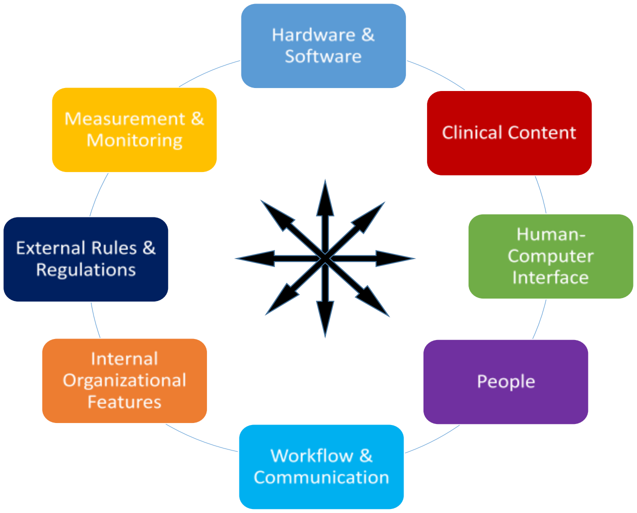
The focus on improving outcomes by utilizing HIE was announced in 2009 when the Health Information Technology for Economic and Clinical Health (HITECH) Act established the Medicaid and Medicare incentive programs to incorporate electronic certified technology into healthcare (DesRoches et al., 2008; Hillestad et al., 2005; Middleton et al., 2005). These programs were created with the objective of utilizing technology to better inform healthcare clinicians, organizations, and public health entities with the information needed to enhance patient care and patient health outcomes. An example of this is the ongoing expansion of HIE across U.S. healthcare settings (DesRoches et al., 2008; Williams et al., 2012). Persons with chronic illness, especially those living with HIV, could benefit greatly from allowing their PHI to be shared with their clinicians via HIE. Identifying HIV-positive patients that are out-of-care and having the ability to send electronic alerts to their healthcare providers are innovative usages of HIE. In NYS, an “opt-in” or signed consent model is used to obtain HIE consent. In this chapter, we describe a sociotechnical analysis using mixed methodologies to further what is known about the factors affecting PLWH consenting to HIE. The purpose of this study was to describe the sociotechnical context of HIE consent in an HIV clinic.

Conceptual Model

Our study is guided by Sittig and Singh’s Eight Dimension Sociotechnical model (Sittig & Singh, 2010). This model is comprised of eight dimensions (Figure 7) and provides an understanding of HIT interventions, work processes, and concurrent fluidity between its various domains (Sittig & Singh, 2010). The sociotechnical domains are not independent of one another but rather mutually supporting and simultaneously influential of one another. For example, hardware cannot be utilized without people to run the software, which is dependent on the human computer interface interaction. Utilizing a sociotechnical approach is premised on the interrelationship between technology and social aspects involved in contributing to the formation of new technical knowledge within the context of designing complex HIT-related interventions (Sittig & Singh, 2010). Specifically, these eight domains are: (1) Hardware and software, (2) Clinical content, (3) Human-computer interaction, (4) People, (5) Workflow and communication, (6) Internal organizational policies, procedures and culture, (7) External forces: rules, regulations and pressures, and (8) System measurement and monitoring.

We contextualized and defined these domains with the overall intent to describe how these interrelated domains inform next steps and possible future recommendations for HIE informed consent-related interventions. Hardware and software refer to the physical and technological structures in place that support HIE at the clinic. An example of this would include clinic registration software used to document and track those persons who have consented to HIE. Clinical content is inclusive of all structured and unstructured data elements. In our study, we used electronic patient demographic and consent data as resources to assess consent rates within the clinic population. Human-computer interface refers to all end-user audio, visual and tactile interactions with the system. This is the user’s interaction with the system. People represent all stakeholders involved in the HIE consent processes. Workflow and communication describe the collaborative processes needed to integrate HIE consent into daily clinic registration activities. Internal structural policies and procedures are those that are exclusive to the large, urban academic hospital organization. Lastly, external forces: rules and regulations are guidelines set at the federal and state level that influence an organization’s priorities. When synthesized, these dimensions represent how interrelated processes can elucidate the core of an issue and also inform the design and development of meaningful interventions. The sociotechnical model guided the exploration and informed the overall study design. Analysis of clinic workflow and interviews with key stakeholders were used to explore the complex social aspects of how work and technology are integrated at this clinic. This provided a holistic view of work processes and contributed to new knowledge in the design of an improved way to facilitate HIE consent.

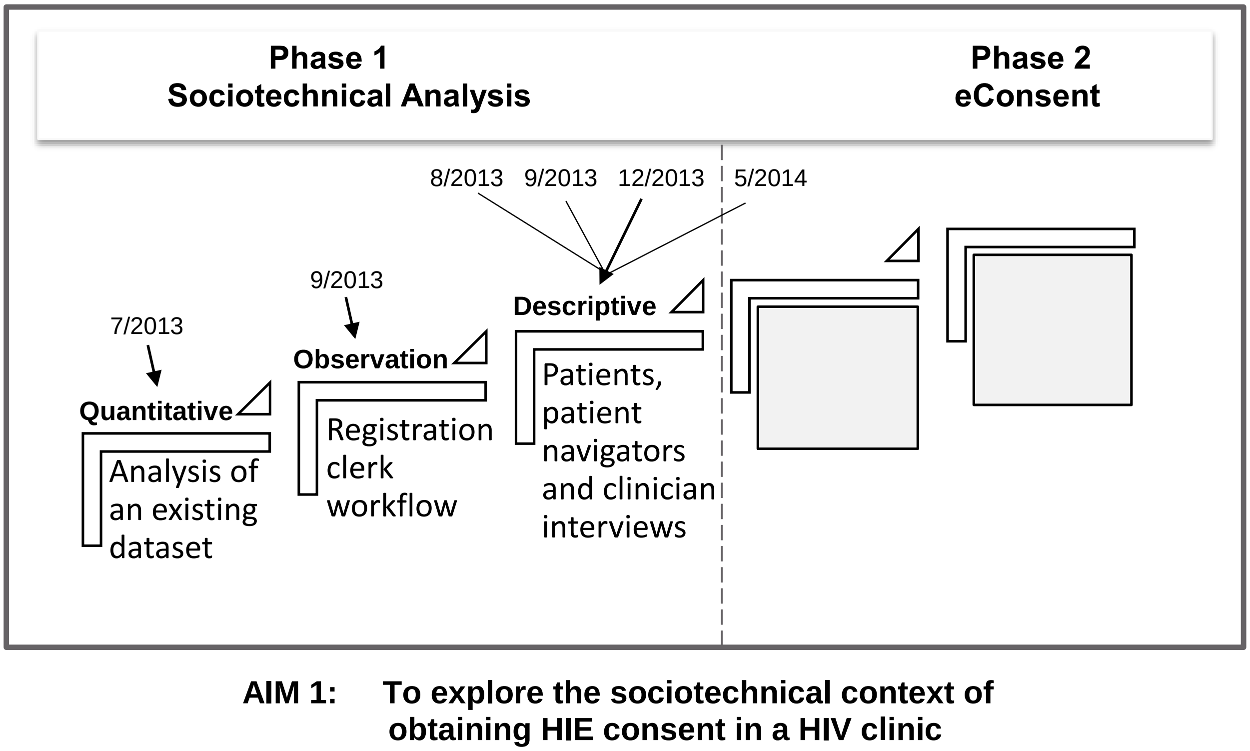
Figure 7. Illustration of the interrelated nature of the sociotechnical domains.



Methods

Building upon the work of previous studies that explored factors affecting PLWH's willingness to share their PHI electronically (Dimitropoulos et al., 2011; Teixeira et al., 2011; Whiddett et al., 2006), we conducted a mixed methods study utilizing multiple data sources. The Eight Dimension Sociotechnical Model was used to analyze the interrelated factors that affect HIE consent at the clinic. In order to accomplish this, data from an existing multi-site survey was used to explore with which types of healthcare personnel PLWH were most willing to electronically share their PHI (Gordon et al., 2012). All other data came from a single HIV clinic that was one of the settings for the survey. Clinic registration staff were observed to explore the workflow processes in obtaining HIE consent from HIV clinic patients during registration. This observational data was then complemented with qualitative interview data from patients, registration clerks, clinicians, and patient navigators on factors affecting PLWH in consenting to HIE. The results obtained through the data guided the next steps of how to best facilitate the HIE consent process at the clinic (Figure 8).

Figure 8. Illustration of Phase 1 / Aim 1



Setting

All data except for the survey data were collected at one HIV clinic that included SelectHealth members. Additional surveys were collected from other SelectHealth members at other clinics. SelectHealth is a NYS, Medicaid managed care health plan for PLWH. All qualitative data (i.e. observations, interviews, and focus groups) were obtained at one urban, large academic hospital's HIV clinic in New York City. Approximately 1,661 PLWH are in care at this clinic, with the majority of the population insured through Medicare, Medicaid, and Medicaid special needs plans for HIV (e.g., SelectHealth). The HIV clinic has a comprehensive staff consisting of: (1) primary care physicians, (2) a gynecologist, (3) a neurologist, (4) psychiatrists, (5) nurse practitioners, (6) medical fellows, (7) registered nurses, (8) social workers, (9) a nutritionist, and (10) a medication adherence patient educator (Table 4).

Table 4

HIV clinic staff characteristics.

Specialty	**Full-time**	**Part-time**
Primary Care	5*	11
[a]Gynecologist		
Neurology	0	1
Psychiatry	1	1
Nurse Practitioner	4	1
[b]Fellowship	0	7
Registered Nurse	2	0
Social Worker	4	0
Nutrition	1	0
Medication Adherence Education	1	0

[a]Gynecologist is also full-time primary care provider.
[b]HIV/Infectious disease 1st, 2nd and 3rd year medical fellows.

Procedures

Data were collected, and mixed methods were used to better understand the facilitators and barriers of PLWH consenting to HIE in NYS. Methods employed were: (1) ecological scan, (2) system measurement and monitoring, (3) PLWH survey, (4) focus group and key informant interviews, and (5) observations (Table 5).

Ecological scan

An ecological scan was used to identify external and internal influences on consent for HIE that provided important context for understanding HIE consent in our setting. In this study, the ecological scan included the assessment of both internal and external environmental influences relative to HIE consent for PLWH (Graham, Evitts, & Thomas-MacLean, 2008). Internal sources of information include organizational documents (clinic HIE consent), electronic data sources (clinic HIE consent rates), and survey data (demographic questionnaire). We explored the clinic operating policies and procedures through their electronic portal, the

‘Infonet,’ which is governed by the larger hospital organization. External sources of information included the current NYS HIE policies (Kern et al., 2009; NYeC, 2012), the governing rules and regulations of Meaningful Use (Blumenthal & Tavenner, 2010), and HIPAA (Steinbrook, 2009).

System measurement and monitoring via clinic consent rates

System measurement was operationalized as HIE consent rates for the HIV clinic patients, which were obtained by contacting the clinic’s administrative manager. This data was retrieved from the clinic’s patient registration software. Clinic patient HIE consent rates were summarized with descriptive statistics.

ACASI survey of PLWH willingness to share PHI

As part of the Health Resources and Services Administration (HRSA)-funded electronic network system collaborative, a survey was administered to PLWH to understand the factors that influence the decision to share PHI (Whiddett et al., 2006). Following institutional review board (IRB) approval at both Columbia University Medical Center and University of California San Francisco (the coordinating center for the collaborative), a convenience sample of 291 PLWH were recruited from the SelectHealth membership. Recruitment strategies included: (1) mailing prospective participants information about the study, (2) inclusion of study information in the Select Health newsletter, (3) direct contact via telephone, and (4) posted flyers in the patient common areas in clinic or community-based organization settings. Participants answered survey questions using Audio Computer-assisted Self-interviewing (ACASI) software in their language preference (English or Spanish). This method of obtaining survey responses has been shown to reduce social desirability and response bias in PLWH (Adebajo et al., 2014; Johnson et al., 2001). Survey domains included sociodemographic characteristics, clinical status, quality of life, perceived stigma, patient-provider communication, and internet use. In addition, patients’ ratings of willingness to share PHI with various recipients using a secure electronic network were obtained (Whiddett et al., 2006). Data were analyzed using descriptive, correlational methods including logistic regression with four dependent variables.

Focus groups and key informant interviews

Focus groups and key informant interviews were obtained to better understand patient, patient navigator, and clinician perceptions about the facilitators and barriers that influence PLWH willingness to consent to HIE at the HIV clinic. Prior to initiation of all study procedures, approval was received from the Columbia University IRB. A convenience sample of 23 stakeholders (PLWH, n = 12, clinic registration clerks, n = 4, clinicians, n = 4, and patient navigators, n = 3) were recruited from an urban New York City HIV clinic to explore the barriers and facilitators of HIE consent. Recruitment strategies included: (1) direct contact with all stakeholders, (2) posted flyers in the HIV clinic common patient areas, (3) direct email to patient navigators, and (4) an announcement about the study at a clinician staff meeting. An open-ended interview guide was used for the key informant semi-structured and focus group interviews. All interviews were audiotaped, professionally transcribed verbatim, and analyzed thematically to describe the perceived facilitators and barriers to HIE consent. Re-occurring responses were grouped into categories. Discrepancies were discussed by the research team until consensus was reached.

Workflow observations

Workflow observation using the technique of contextual inquiry (Beyer & Holtzblatt, 1997; Ho, Aridor, & Parwani, 2012) was employed to capture disarticulated work processes from the clinic registration clerks. The four components of contextual inquiry are: (1) gaining context by going where the work is being performed, (2) articulating the work experience through shared inquiry, (3) clarifying observational findings with participants, and (4) maintaining focus with the topic of interest (Beyer & Holtzblatt, 1997). Observations were conducted on two separate workdays at the clinic. Three observers documented the workflow processes of the four registration clerks over a two-day period during one morning session and afternoon clinic hours. A flow chart and a sequence diagram were created that described the clinic registration processes.

Table 5

Summary of concepts, definitions, methods, and samples organized by sociotechnical model.

Concepts	**Definition**	**Data Collection and Analysis Methods**	**Sample**
Hardware/Software	Hardware and software used to support HIE	Ecological scan (internal) : Descriptive statistics of HIE consent from EHR software, and electronic survey data using logistic regression	Consent data on EHR software Survey data
Clinical content	Structured and unstructured clinical data that is stored in the system	Ecological scan (internal) : Descriptive statistics of HIE consent data from EHR software	N = 1,661 HIV clinic patient data
Human Computer Interface	User's interaction with the system	Ecological scan (internal) : registration clerk observation using contextual inquiry	N = 4 registration clerks
People	Stakeholders involved in HIE consent process	Survey, focus groups, key informant interviews Descriptive statistics and logistic regression of PLWH survey data Thematic analysis of focus group and interview data	PLWH, registration clerks, clinicians, patient navigators
Workflow and communication	Interaction and collaboration with clinic staff and their use of information technology	Observation with contextual inquiry, key informant interviews	N = 4 Registration clerks
Organizational policies and procedures	Internal structural policies and procedures	Ecological scan (internal) : Document review and narrative summary of organizational policies and procedures from the hospital organizations 'Infonet'	Organizational online policies and procedures via 'Infonet'
External forces: rules, regulations, and pressures	HIE, HIPAA and Meaningful Use federal and state legislation	Ecological scan (external) : Document review and narrative summary of NYS rules and regulations for HIE, HIPAA, & The Meaningful Use Initiative	NYS guidelines for HIE HIPAA The Meaningful Use Initiative
System measurement and monitoring	Use of HIE consent	Summary of HIE consent data using descriptive statistics	1 year of HIV clinic consent rate data

Results

The study sample include patients, patient navigators, and registration clerks who identified as non-white Hispanic or African American. This population is representative of our urban community and those which are most affected by HIV (Table 6) (CDC, 2012d).

Table 6

Demographics of study participants.

Variables	Clinic Patients N = 12 *Focus Group	Registration Clerks N= 4 *Interviews	Clinicians N= 4 *Interviews	Patient Navigators N= 3 *Focus Group	PLWH Survey N=291
	n (%)	n (%)	n (%)	n (%)	n (%)
Gender					
Male	9 (75)	0	1(25)	1(33)	187 (64)
Female	3 (25)	4 (100)	3 (75)	2 (67)	104 (36)
Race					
African American	10 (83)				159 (55)
Asian American/Pacific Islander					2 (1)
Native American					9 (3)
White			4 (100)		36 (12)
Other	2 (17)				85 (29)
Ethnicity					
Hispanic	2 (17)	4 (100)	0	3 (100)	71 (24)
Not Hispanic	10 (83)	0	4 (100)	0	219 (75)
Unsure					1 (1)
Education	N/A	N/A	N/A	N/A	
<High School					105 (36)
>= High School					186 (64)
Immigrant	N/A	N/A	N/A	N/A	
Yes					63 (22)
No					228 (78)
					^{a}M (SD)
Age (in years)	N/A	N/A	N/A	N/A	46.77 (9.16)

^{a}M (median) ; SD (standard deviation)

Findings from this study elucidated the factors that influence HIE consent in an HIV clinic. These factors are illustrated in the order of the sociotechnical framework (Sittig & Singh, 2010). Concepts in our study included: (1) hardware and software, (2) clinical content, (3) human computer interface, (4) people, (5) workflow and communication, (6) organizational policies and procedures, (7) external forces: rules, regulations and pressures and (8) system measurement and monitoring.

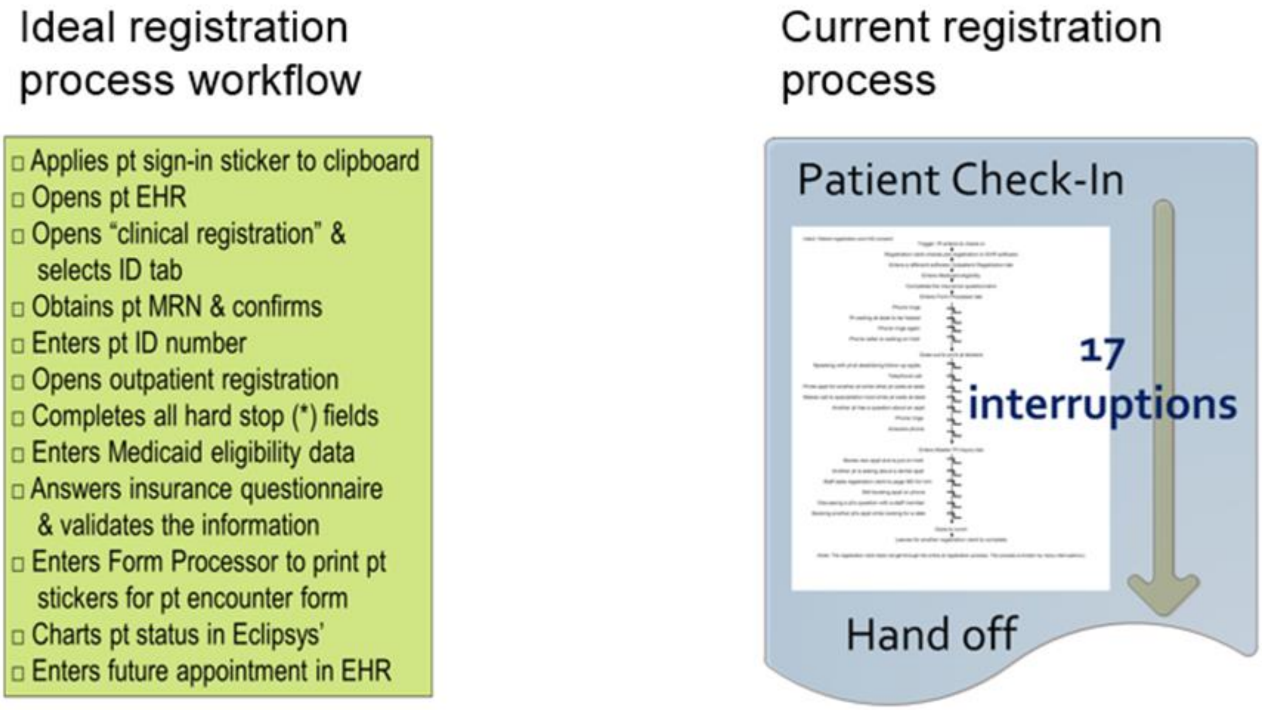
Hardware and software and clinical content

The hardware used for the clinic registration includes a one screen desktop computer and multiple software applications. The process of registration is triggered by the registration clerks logging in to three different registration software systems. The first software system, *Eagle 2000*, is used for patient registration and real-time insurance eligibility verification through the Department of Health. The second software program, Allscripts, is used to enter the patient's medical chart and alert the healthcare provider that the patient is ready to be seen. Lastly, the third software program, *Sorian*, is used to schedule follow-up visits after completion of their current medical encounter. Eagle 2000 and Allscripts are used consecutively at the beginning of patient registration. Sorian is used at the end, after the patient's medical visit. These three software programs include all information that is stored in the electronic system (Sittig & Singh, 2010) and are used solely to complete the electronic registration processes.

Human-computer interface

At this HIV clinic, it was the responsibility of the registration clerks to obtain HIE consent from the patients. Exploration of their workflow through observation was critical to identify what facilitators and barriers exist to HIE consent. Observation revealed disarticulated workflow and other factors that influenced discussing and obtaining HIE consent. An ideal registration process workflow consisted of multiple tasks to register a patient into the clinic to visit their clinician. In addition to registering patients, HIE consent was to be obtained as well. Observations of the four registration clerks were conducted during the patient registration process over the course of two days, and 17 interruptions during one patient registration encounter was noted (Figure 9). We highlight one registration clerk's workflow, since there were no differences noted in the amount of interruptions and workflow barriers encountered when compared to the other three clerks. For example during the observations, the two other registration clerks encountered the same barriers, such as interruptions caused by multiple phone calls, patients, physicians and other clinic staff requiring assistance. Also, important registration materials (patient stickers and forms) were not readily available in the direct workspace area (Figure 10). Three different program logins were required to complete the registration process as noted above (*Eagle 2000, Allscripts/Eclipses, and Sorian*). Barriers identified during the workflow observations were the multiple logins required and the very busy work environment within which interruptions disrupted the completion of the registration in one sitting (Figure 9).

Figure 9. Illustration of an ideal registration process workflow and the current registration process.



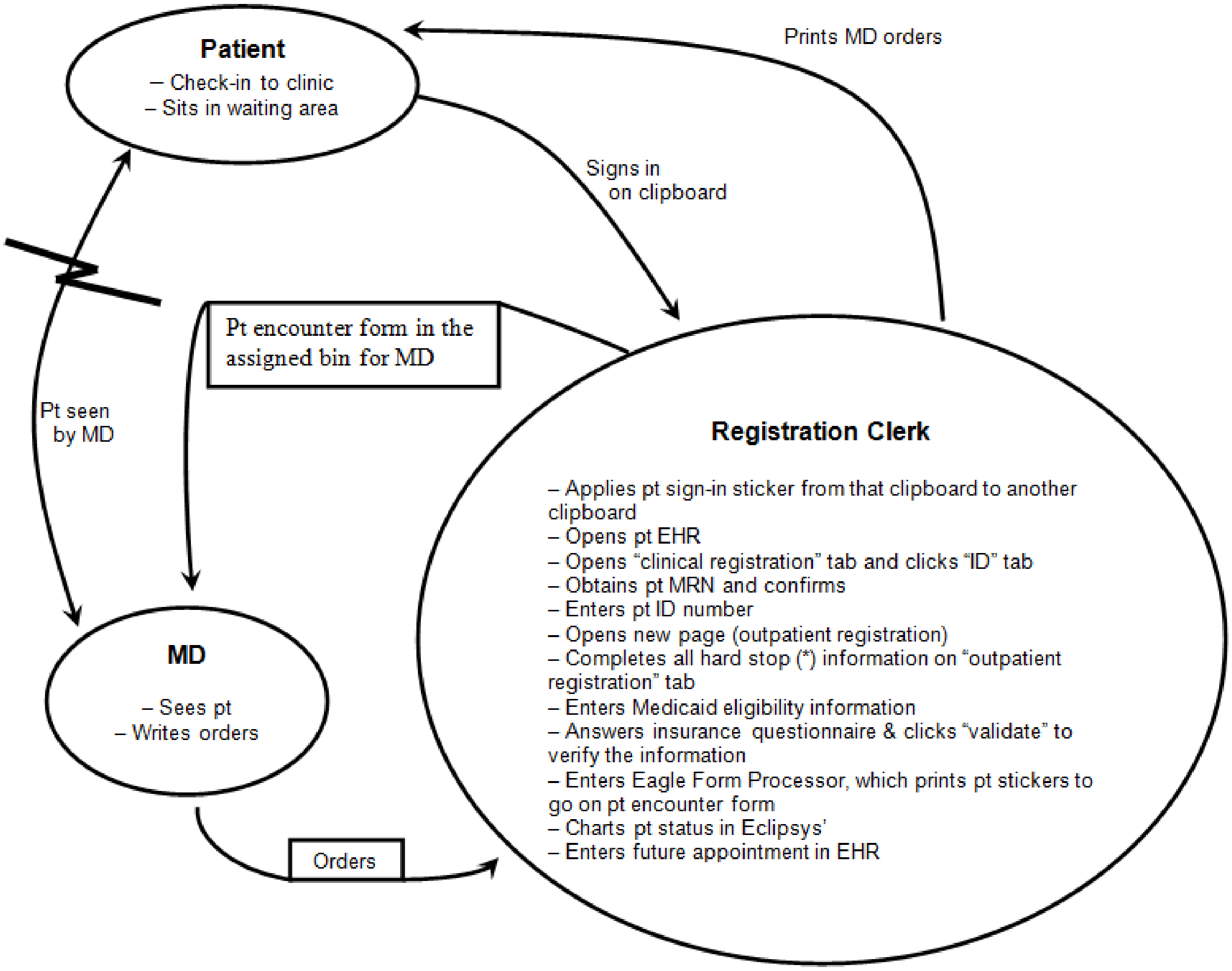
Ideal registration process workflow

- ☐ Applies pt sign-in sticker to clipboard
- ☐ Opens pt EHR
- ☐ Opens "clinical registration" & selects ID tab
- ☐ Obtains pt MRN & confirms
- ☐ Enters pt ID number
- ☐ Opens outpatient registration
- ☐ Completes all hard stop (*) fields
- ☐ Enters Medicaid eligibility data
- ☐ Answers insurance questionnaire & validates the information
- ☐ Enters Form Processor to print pt stickers for pt encounter form
- ☐ Charts pt status in Eclipsys'
- ☐ Enters future appointment in EHR

Current registration process

*Full illustrative view of current registration process in Figure 11.

Figure 10. Flow chart diagram of registration process workflow.



People

The stakeholders involved in this study included registration clerks, patient navigators, clinicians, and PLWH (Table 6). Patients are those receiving HIV care at the clinic, and they have the option of consenting to HIE. However, those interviewed were not familiar with the process of obtaining HIE consent or the clinic's paper HIE consent form. Patients were not aware due to low exposure to the forms as demonstrated by the registration clerks having too many competing demands in their workflow to obtain consent.

Registration clerks are the initial point of contact for patients at the clinic. They have multiple responsibilities, of which patient registration is the most important. Due to their busy work environment, it is uncertain at what level registration clerks understand the concept of HIE (i.e., how HIE works, its benefits to patients, the consent model for "opt-in" states, such as NYS).

The role of the patient navigators is to assist HIV clinic patients with becoming more independent and adherent with their HIV care. Patient navigators work with patients to improve their medication adherence, and they also accompany them to other non-HIV clinic appointments. Patient navigators also provide encouragement and a listening ear to the HIV clinic patients (Koester et al., 2014). This demonstrates the respect and trust that the HIV clinic patients have for patient navigators. Focus group data revealed that patient navigators were not very familiar with the concept of HIE or the HIE consent process because it was not a part of their work responsibilities. For example, HIE was described as medical providers accessing patient data, but the patient navigators could not articulate the steps to obtaining consent or where the information was accessed.

Clinicians do not directly discuss or obtain HIE consent from the patients. Focus group data from both clinicians and patients suggested that both stakeholders wanted to optimize their time with reviewing CD4 lab results, etc. and did not want to limit that time by discussing HIE consent. Since obtaining HIE consent is an organizational initiative and not a policy, clinicians are not too involved in the process since the registration clerks are responsible for obtaining patient consent. Clinicians utilize HIE to access patient data that is currently accessible, and they have varying direct or indirect involvement in the processes. For example, there are some clinicians that are actively involved in the organization's HIE initiative committees, while other clinicians may briefly mention HIE to patients or may be unaware of the consent process in general.

PLWH willingness to share their protected health information

In our regression model to assess PLWH willingness to share their PHI, we found that most PLWH are willing to share their PHI with healthcare personnel (Table 7). The results indicated that those who are U.S. born were more likely to share all of PHI electronically with specific healthcare personnel. No other relationships regarding age, gender, being US born, ethnicity, sexual orientation, education and annual income were significant.

Table 7

Correlates of willingness to share PHI from PLWH survey.

Independent Variables	Dependent Variables			
	Non-HIV Specialists (Cardiologists/OBGYN, etc.)	Emergency / Hospital Personnel	Primary Care Provider	Registered Nurses / Medical Assistants
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Age	1.018 (0.988 – 1.048)	1.001 (0.968 – 1.035)	1.002 (.965 – 1.041)	1.016 (.982 – 1.050)
Gender	0.559 (0.304 – 1.028)	1.059 (0.544 – 2.062)	1.144 (.519 – 2.522)	.869 (.443 – 1.704)
U.S. born	2.504* (1.372 – 4.569)	3.080* (1.633 – 5.810)	1.445 (.673 – 3.106)	1.905 (.981 – 3.699)
Ethnicity	1.031 (0.559 – 1.903)	1.294 (0.636 – 2.634)	1.101 (.486 – 2.492)	1.039 (.520 – 2.079)
Sexual Orientation	1.214 (0.673 – 2.192)	1.175 (0.599 – 2.303)	1.459 (.674 – 3.155)	0.818 (.411 – 1.628)
Education	1.125 (0.596 – 2.146)	1.189 (0.581 – 2.433)	0.624 (.268 – 1.397)	0.864 (.431 – 1.733)
Income	1.047 (0.511 – 2.146)	0.807 (0.370 – 1.762)	0.612 (.268 – 1.397)	0.932 (.422 – 2.056)

Note: * p-value <.05

Stakeholder interviews

Barriers and facilitators (Appendix A) are summarized in Table 8 along with representative quotes from stakeholders. Barriers such as lack of trust and limited understanding of HIE were shared across multiple stakeholders, whereas some barriers were unique to a particular stakeholder group. For example, discrimination was a barrier to patients consenting to HIE because of prior experiences where positive serostatus negatively affected the care they received from clinicians (Derose et al., 2007; Teixeira et al., 2011; Whiddett et al., 2006). Additionally, some patients were confused or uncertain about the differences between HIE and

HIPAA. A facilitator that was noted across all participants was having a dedicated person discuss HIE consent. Due to the trusting relationship that patients have in the patient navigators, they may be ideal personnel to discuss HIE with the clinic patients.

Table 8

Selected utterances of the facilitators and barriers that affect HIE consent.

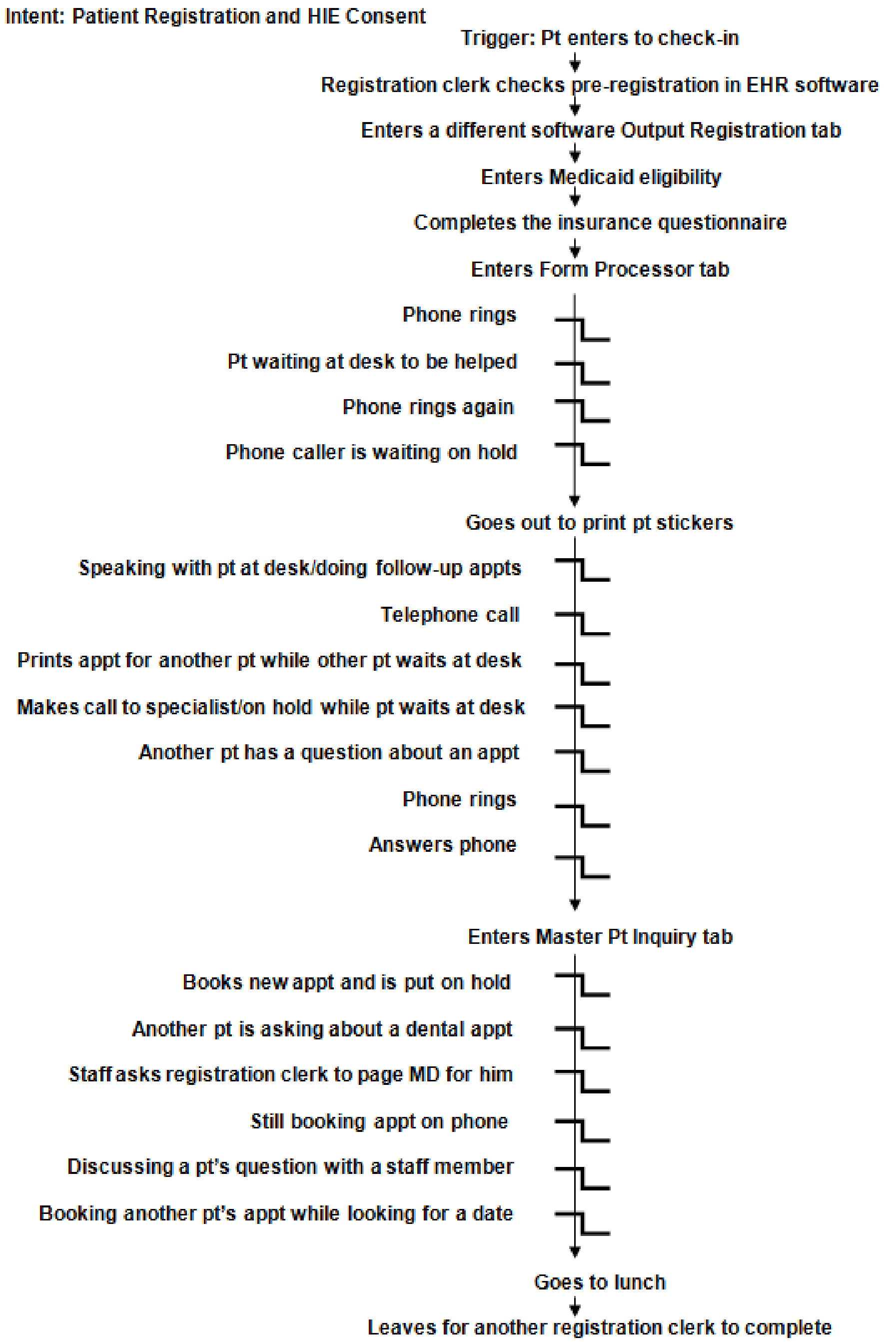
Barriers	
Trust	"*I think that I need to be in control about who I want to share my HIV status with. And maybe some doctors, they really just don't need [to know]. I mean you know I don't have an issue with it. If you don't need to know it, then I don't want to share that information". – Patient*
	"We had one patient who refused to sign, due to the fact that he didn't want his information in the computer system or on the internet, so to speak. He was concerned about if it gets hacked or if it gets tampered with. You know it would be; what's the consequence for that? So he basically denied or just agreed not to sign the health exchange form." – Registration Clerk
Limited Understanding/ Confusion with HIPAA	*"And also [patients] really not quite understanding, maybe not quite understanding what it means. Like, what do you mean my information will be shared? I don't know what [the current] process of explanation. And again, this goes back to the time issue, if you're really going to be available to answer people's questions, now you're talking about a time-consuming process." – Clinician*
	"Just like the HIPAA almost, no?" - Patient
Facilitators	
Dedicated Person	*"So if there would be one other person who would be a little more designated... Right, to handle this kind of stuff, then I would feel more comfortable because doctors are usually sometimes; they're not always up-to-date on paperwork stuff." – Patient*
	"I was doing this in the beginning when they just started [HIE consent] here. Believe me; I got maybe 98% of the patients to sign the consent, because I was sitting with the patients myself. And I was explaining to them what was going on and why. And how they're going to benefit with it, ok? So that's the answer." – Registration Clerk
	"I think education is the key to everything. You know, you explain to people why you've got to do something or why we feel that it's good for you to do X,Y and Z. If you don't explain it to them in terms of like how does this benefit me? They they're not going to [understand] you know what I mean?"– Patient Navigator
	"You know I think you can get at those issues and explain them and get people to consent with a dedicated person out there, kind of explaining it and also highlighting it because again they get this big package of paperwork with all of this stuff happening." – Clinician

Workflow and communication

Based on clinic observations, the workflow for HIE consent is represented in Figure 10. Observational findings suggested the following: (1) an overwhelming, high-volume work environment, (2) competing demands between clinicians, patients and the registration clerk's work-related responsibilities, and (3) three different software logins to complete during the registration process.

The sequence model (Figure 11) consists of 17 interruptions during one registration encounter that were barriers to HIE consent discussions. Due to this, it took more than one encounter with a patient to complete the registration process. According to the sequence model, the fragmented workflow resulted in tasks not being completed. Since the registration environment was very busy (i.e., multiple phone calls, appointment scheduling, patient and clinician needs), registration clerks would initiate the registration process and then have patients go to the waiting area until they were able to fully complete registration. During our observation periods, it was not possible for the registration clerks to initiate HIE consent discussions with the clinic patients.

Figure 11. Sequence diagram of registration process.



(Note: The registration clerk does not get through the entire pt registration process. The process is broken by many interruptions.)

Organizational policies and procedures

The internal ecological scan suggested that HIE consent was an initiative and not an actual organizational policy. All new or existing policies and procedures are accessed electronically, such as the HIPAA privacy policy, which states that all employees and staff will appropriately use, manage, and protect PHI by only disclosing the minimum necessary standard to accomplish the intended purpose. Because obtaining HIE consent was an initiative to increase the number of patients that consent to electronically share their PHI and not a policy, staff members may have had limited access to HIE consent-related information.

External forces: rules, regulations and pressures

External forces have the ability to facilitate or hinder the creation of HIE in the clinical setting. Our study focuses on the following external forces: rules, regulations and pressures, such as HIE, Healthix, HIPAA, and Meaningful Use criteria, which are regulated by federal and NYS laws. This captured document review and narrative summary of federal and state initiatives and regulations for electronic sharing of PHI.

Health Information Exchange

New York State governance requires written informed consent to electronically share medical records with clinicians across HIE “opt-in” healthcare settings. One exception to this rule would allow for a qualified entity or participant, such as a provider organization or a practitioner, to ‘break the glass’ and access PHI in life threatening and emergency situations (Ancker et al., 2012; Kim et al., 2015). The Statewide Collaboration Process, which includes the New York eHealth Collaborative (Ancker et al., 2012; Kern et al., 2009), and the NYS Department of Health govern standardized statewide policies and procedures that ensure New Yorkers will benefit from HIE (Kern et al., 2009).

Healthix

Established in 2012, Healthix is the regional health organization that serves the New York metropolitan and Long Island areas (Garg et al., 2014). It provides HIE data for over 10 million patients to healthcare providers, nursing homes, insurers, and others related entities at over 500 locations (Healthix, 2015). Through written informed consent, patient data is accessed and utilized to improve care coordination, medical treatment, and patient outcomes (Healthix, 2015). Three options for HIE consent that are available to the patient are as follows: (1) to consent only in a medical emergency, (2) to deny consent even in a medical emergency, and (3) to give consent for all protected health information to be accessed by their healthcare provider (Healthix, 2015). Healthix is HIPAA compliant as all information is protected by federal and state privacy and confidentiality laws (Healthix, 2015).

Health Insurance Portability and Accountability Act

New York State Public Health Law Article 27-F (Klein, Karchner, & O'Connell, 2002) protects HIV positive patients and the disclosure of confidential HIV serostatus information. As a component of HIE, the HIPAA rule protects an individual’s ‘identifiable health information,’ such as HIV serostatus. In this fashion, an individual is required to consent prior to allowing their HIV serostatus to be shared on a need-to-know basis between their direct care providers. This also pertains to their consent to HIE. New York State has stringent standards with regards to protecting ‘identifiable health information’ and will always supersede the general HIPAA privacy rule. When compared to other non-“opt-in” states, affirmative HIE consent in NYS is required in order to electronically access a patient’s ‘identifiable health information.’

Meaningful Use

The Centers for Medicare and Medicaid (CMS) through the Office of the National Coordinator (ONC) created an incentive program for qualifying providers and organizations to 'meaningfully use' certified EHRs (Blumenthal & Tavenner, 2010; Steinbrook, 2009) with the intention of improving patient experience, care and outcomes. In complying with this initiative, HIE is a mechanism that facilitates meaningful use as it permits the transfer and accessibility of patient health data between healthcare providers.

System Measurement and Monitoring via Clinic Consent Rates

System measurement and monitoring refers to the degree that functions, features and monitoring for prospective outcomes are available (Sittig & Singh, 2010). In our observation of the registration clerks, we observed multiple software logins and an overwhelmingly busy work environment. Because of this, it is unknown if all HIE consent data has been entered into the clinic software system, although one year of HIE consent data was provided from the EHR registration software. When a patient consents to HIE, they must sign a consent form. The registration clerks document this in the EHR by checking a box indicating the patient has consented to share all of their information electronically via HIE. Once this is documented, it interfaces with Healthix, and the paper consent is scanned into the patient EHR. Of approximately 1,700 patients, clinic consent rate data demonstrated that 48% (799) of the patients have consented, 4% (70) have declined, and 48% (792) have neither consented nor denied consent.

Discussion

Implications for improvement of the HIE consent process at the HIV clinic

We conducted a sociotechnical analysis to better understand HIE within the context of an HIV clinic. Triangulation of data sources helped us to identify areas for process change to better facilitate the HIE consent process at the clinic. The methods employed by these studies were guided by the Eight Dimension Sociotechnical Model to describe the interrelated concepts of how to better inform PLWH about HIE at the HIV clinic. Our studies allowed us to illustrate the inter-dependency of the dimensions (e.g., external rules and regulations driving organizational policies and procedures, which dictated the importance of hardware and software on capturing clinical content). Additionally, disarticulated communication was captured by analysis of registration clerks' workflow and interaction with the system. This was corroborated by patient, patient navigator, and clinician interview data. Thus, it is unlikely that there is one single solution, and more importance should be focused on process changes at the clinic via a user-centric intervention. Because the model's dimensions are already well integrated, we found it challenging to contend that one dimension would adequately describe a theme. Therefore, we aggregated our themes and provided a comprehensive discussion organized by the most relevant dimensions: (1) Clinical content: barriers, (2) Human-computer interface: workflow challenges, (3) People: "opt-in" challenges.

In regards to clinical content, our analysis of existing data suggested that PLWH are willing to electronically share their PHI with specific healthcare personnel. This is important as HIE is an important facilitator in supporting the continuum of care. Additionally, since PLWH are willing to electronically share, it is important to now obtain a better understanding of barriers that exist to PLWH electronically sharing PHI, as it remains unclear how to best facilitate this process.

It was revealed during our study that a registration clerk's interaction with the system was time consuming due to the multiple program logins required to register one patient at the clinic. This was a workflow challenge that affected obtaining consent. Figure 7 detailed the processes of registration at the clinic, and Figure 8 described registration interruptions. These processes reaffirmed our stakeholder interview data, which suggested that having a dedicated person may be beneficial for PLWH at the clinic.

Petchey and colleagues's (Petchey, Farnsworth, & Heron, 2001) survey on confidentiality policy and procedures of HIV status revealed that PLWH had the greatest resistance to receptionists (70%), practice managers (48%), counselors (37%) and practice nurses (36%) knowing their positive serostatus. Additional studies have found that PLWH are willing to share their serostatus via HIE with essential need-to-know clinicians (Maiorana et al., 2012; Patel et al., 2011; Teixeira et al., 2011). In terms of communication, efficiency is hindered due to the overwhelming registration area environment. This reiterates the need for further exploration into who are optimal personnel to discuss and obtain patient consent.

In exploring NYS external rules, regulations, and pressures, it was interesting to note that there are regulations that standardize HIE and how 'identifiable health information' is accessed and utilized, how NYS law supersedes the HIPAA privacy rule, and how Meaningful Use's intention is to improve a patient's experience, care, and outcomes. Currently, there are no recommendations in place that assert who would be the appropriate personnel to obtain HIE consent from patients. In our study that utilized observation and stakeholder interviews, registration clerks were responsible for obtaining HIE consent, and our results suggest that their overwhelming, high-volume work environment was a barrier obtaining to HIE consent.

However, we did identify that although patient navigators have limited knowledge of the process of HIV consent at the clinic, their relationship with clinic patients extend beyond navigation of the healthcare system. Thus, the extent to which patient navigators should be involved in patient HIE consent is unclear and necessitates further exploration. Moreover, nationally there are seven affirmative consent states and the other states abide by an “opt-out” (automatically in HIE) model or a have a hybrid combination of “opt-in” and “opt-out” rules (Gray, 2011). Recommendations for “opt-in” state-specific standardization of HIE consent procedures has the promise of facilitating greater participation.

Additionally, patient focus group data suggested that the distinction between HIE and HIPAA was unclear. This could be partly due to a few significant factors, such as the lack of exposure that patients have to HIE consent discussion due to the overwhelming workload of the registration clerks and the limited understanding and confusion about HIE within our HIV clinic population (Table 4). Although we have identified key barriers to HIE consent at the clinic, the best means of obtaining consent remains unclear. Based on barriers and facilitators to consent at this clinic, patient navigators may be key personnel to obtain consent because they are trusted and integrated into the lives of the clinic patients.

Demographic data collected from the PLWH survey study (Table 6) described a mostly non-Hispanic, African-American population. Other studies that explored patients’ perceptions towards sharing their medical data electronically had an overrepresentation of Caucasian or respondents of European descent (Dimitropoulos et al., 2011; Patel et al., 2011; Weitzman, Kelemen, Kaci, & Mandl, 2012; Whiddett et al., 2006), which is in contrast to our sample of underrepresented, racial and ethnic minority populations. Hence, factors that influence one's willingness to share their PHI electronically may vary based on race and/or ethnicity. This finding indicates a need for further insights on PLWH's understanding of HIE, HIE's implications, and the role of healthcare personnel in facilitating discussion about the patient-centered benefits of HIE.

Multiple studies have suggested that immigrants have less accessibility to healthcare coverage (Derose et al., 2007; Saint-Jean, Dévieux, Malow, Tammara, & Carney, 2011; Stimpson, Wilson, & Su, 2013) than those who are U.S. born due to existing and new healthcare policies. Issues of perceived HIV stigma, discrimination, lack of English proficiency, and inadequate healthcare coverage are influential to an individual being unwilling to share their personal medical data (Derose et al., 2007; Teixeira et al., 2011; Whiddett et al., 2006). Conversely, U.S. born individuals are not overwhelmingly impacted with challenges such as limited English language proficiency and additionally have access to formal education. Subsequently, this may be a reason why there has been limited consideration to the role of nativity status and HIE, which further explains why those who are U.S. born are more willing to electronically share their personal medical data than those who are not U.S. born. Solely having U.S. healthcare experience as a patient may facilitate a certain level of understanding in medical situations (Derose et al., 2007) and also facilitate rapport with healthcare personnel that non U.S. born persons do not share due to their level of acculturation.

Recommendations for next steps

Several areas were identified to guide the next steps to better facilitate HIE consent. First, this study is the first to use mixed methodologies and utilize multiple data sources to better understand the facilitators and barriers to HIE consent for PLWH at a NYC urban HIV clinic.

This information revealed many important considerations for moving forward with improving the HIE consent processes. Second, considering the high degree of trust from patients, patient navigators may be the best choice to initiate conversations with patients about HIE consent. Third, the inability of patients to distinguish HIE from HIPAA allude to the urgent need for consent documents that are clear and understandable. Although not measured in this study, health literacy of consent materials should be further explored to better understand what wording or messages will be the most meaningful for PLWH of varying literacy levels. With the rapid uptake of smartphones and tablet technology, perhaps utilizing visual technology may be a suitable supplement to the current paper consent format. Lastly, based on our aggregate study data and in response to Healthy People 2020's initiative to improve population healthcare quality and outcomes through the usage of communication strategies that incorporate HIT (DHHS, 2012), approaches that integrate patient preferences and perspectives may enable PLWH to make more informed choices about consenting to HIE. This should be further studied.

Limitations

The study was conducted at one specific, urban HIV clinic. Even though reassurances were provided to protect confidentiality, patient/provider relationships, and the employment status of patient navigators and clinicians, it is unknown if those factors influenced participant responses during the interviews. Duration of patient HIV status and length of professional experience of clinicians and navigators were not studied but could have influenced interview responses. Generalizability is limited since the results were based on patients and employees of one HIV clinic and may not be representative of other similar populations. Notably and despite the limited generalizability, recommendations for further research are warranted.

Conclusions

By conducting a sociotechnical analysis at the HIV clinic, we were able to better understand the multi-faceted dynamics and interrelated processes that reside in everyday workflow, which affect HIE consent for PLWH. Because of this, our study has enabled us to gain significant insights about the barriers and facilitators to HIE consent by gaining first-hand knowledge of the current workflow processes. This data will guide our next step, which is to better inform PLWH at this HIV clinic about HIE and HIE consent.

Chapter Four

A User-Centric Approach to Electronically Inform Persons Living with HIV about Health Information Exchange

Overview

Phase 1 of the dissertation identified barriers to HIE consent for PLWH including: (1) limited understanding about HIE, (2) inability to distinguish HIE from HIPAA, and (3) fragmented registration clerk clinical workflow. To address the first two issues, the decision was made to create and pilot test an electronic consent for HIE.

The decision to design an electronic consent was informed by multiple perspectives. First in terms of a general approach to the design of the eConsent, the primary influence was Wilbanks' work on a three-tier approach to eConsent that was subsequently adopted for inclusion in the Apple Research kit (Ritter, 2015; Sage Bionetworks, 2015a, 2015b). Second, the Cognitive Theory of Multimedia Learning (2009) provided important principles to guide the creation of a simple, intuitive, and interactive eConsent (Mayer, 2009). Third, heuristic techniques guided the eConsent interface design (Goldstein & Gigerenzer, 1999). Fourth, the principles of user-centric design were used to select icons suitable for inclusion in the first layer of a three-tier approach (Årsand & Demiris, 2008).

Research by Wilbanks and colleagues was focused on chronic illness, tracking of symptoms, and various health statuses of consented participants and has led to the creation of eConsent apps for Parkinson's disease, diabetes, and asthma (Hermosilla, 2015; Ritter, 2015; Sage Bionetworks, 2015b). However for this dissertation study, the sole focus will be on the creation of an eConsent that utilizes a three-step layered process: (1) icons that convey important elements of consent, (2) simple text designed to easily describe the information, and (3) a generated pdf copy of the consent paper document (Sage Bionetworks, 2015a, 2015b). This layering process has the potential to facilitate better delivery of HIE consent-related information, which may improve PLWH's ability to make more informed decisions about electronic sharing via HIE.

This approach was further complemented by integrating Mayer's Multimedia Principles, which included: (1) coherence, (2) signaling, (3) spatial contiguity, (4) multimedia, and (5) personalization (Mayer, 2009). The coherence principle refers to the omission of extraneous words and information, which may act as a barrier to information delivery (Mayer, 2009). Signaling utilizes cues to highlight information that inform the user of the organization of the material, such as the icons used in the eConsent (Mayer, 2009). This would be demonstrated by participants using icons that refer to the simple text, which describes the need-to-know components of electronic sharing via HIE. Multimedia utilizes more than one medium for learning, such as pictures and text, instead of relying on solely one method (Mayer, 2009). This dissertation study utilized both. Personalization means presenting words in an informal, lay format that reduces the complexity of formally worded information (Mayer, 2009).

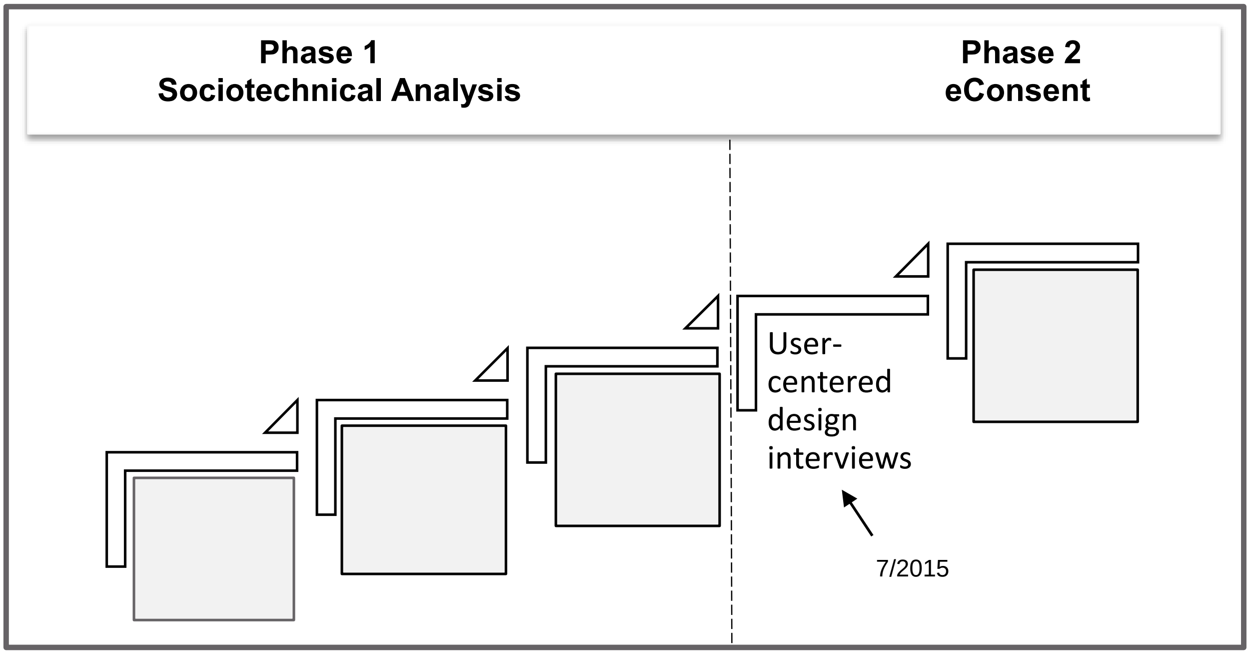
Third, a heuristic decreases decision-making time and permits individuals to continue working through a task without much cognitive effort (Goldstein & Gigerenzer, 1999). A heuristic can be thought of as a mental shortcut. Recognition, a form of memory retrieval, allows individuals to navigate familiar information with the assistance of cues to respond to an answer or to make a decision (Nielsen, 2005). Thus, a recognition heuristic refers to the ability to make quick and efficient decisions using low cognitive effort by making inferences based on partial recognition (Goldstein & Gigerenzer, 1999). For instance when designing the eConsent app, a recognition heuristic supported ease of use and usability through navigation of minimalist design via highlighted icons and visible user functions, such as ‘home page’ and ‘next’ buttons (Goldstein & Gigerenzer, 1999).

Fourth, a user-centric approach (Årsand & Demiris, 2008) was employed to design and integrate technology into the clinic’s HIE consent processes. Currently, there are no community-centered or user-centric validated measures to facilitate initiation, discussion, and obtaining of patient informed consent (Alper, 2015; Rothwell et al., 2014). Consent and other health-related materials are written by medical experts or attorneys, and patients have chronically been misinformed as to the purpose, risks, benefits and procedures of consent (Rothwell et al., 2014). Most consent documents have post-high school reading levels, which are neither helpful nor applicable to many populations (Doak et al., 1996). In contrast, a user-centered approach engages the intended users of the eConsent in the design process.

This research has the potential to inform recommendations and initiate conversations about the benefits of integrating eConsent procedures in HIE “opt-in” states. This could influence existing consent procedures for other chronic disease populations and facilitate better comprehension of consent literature through interactive, eConsent-based applications, all of which may also improve informed decision making for patients (Rothwell et al., 2014).

This study comprises the building of an eConsent app prototype and pilot testing in a sample of PLWH not involved with the design of the app. The methods and results of the two phases are presented sequentially, since the first phase directly informs the pilot testing (Figure 12).

Figure 12. Illustration of Phase 2 / Aim 2



AIM 2: To apply a user-centric approach to design a HIE eConsent for PLWH at a HIV clinic

Building an Electronic Consent through User-centric Design

Aim II: To apply a user-centric approach to design an HIE eConsent for PLWH at a HIV clinic.

Research Design

This cross-sectional, descriptive, qualitative study employed semi-structured interviews to better inform the researcher as to which icons and simple text phrases best described features important to HIE consent. Icon examples using health-related clip art and simple text about HIE was presented to participants. Their feedback informed the iterative design of an iPad eConsent application.

Methods

Human subjects protection

Columbia University Medical Center Institutional Review Board (IRB) approval was obtained before initiating any study procedures. Due to the nature of the semi-structured interviews that explored icon and simple text selection and the desire to maintain confidentiality regarding HIV status, an information sheet was used instead of a consent form with signature. Additionally, information sheets that contain concise information may be more beneficial than those that are extensive and wordy (Jadad & Enkin, 2008). Participation was voluntary, and patients were informed that their care at the clinic would not change due to their decision to participate or decline participation in the study. Prior to the start of data collection, the information sheet was reviewed, and participant concerns were thoroughly addressed.

Setting

The study was conducted at an urban, academic, medical center’s HIV clinic which serves approximately 1700 patients. This clinic is part of the ambulatory care network (ACN) that provides HIV care to patients receiving federal (Medicare or AIDS Drug Assistance Program [ADAP]) or state (Medicaid) insurance.

Sample

Inclusion criteria for participants include the following: (1) receiving care at the HIV clinic, (2) English speaking, (3) English-language literate, and (4) willing to participate. For the purposes of this study, English-language literacy refers to the ability to read at minimum words with three syllables and sentences with at least 10 words (Doak et al., 1996). The ability to read this study's informed consent and agree to participate would demonstrate an appropriate level of literacy to participate. Exclusion criteria were an inability to read English or communicate in English.

Participants were recruited at the same HIV clinic as in the prior studies. Prior to the initial interviews, flyers with study information were posted in the clinic common areas, and prospective participants were able to call the study-line and leave a voice message. The researcher also recruited participants directly from the clinic common areas.

Data collection

Interested participants who met the inclusion criteria completed the interviews in the clinic conference room. The conference room was a familiar setting and decreased environmental barriers and travel constraints. Moreover, the researcher had an established relationship with this population through previous studies conducted at this clinic over the past three years (Ramos & Bakken, 2013).

Five semi-structured interviews were completed. The interviews lasted no more than 60 minutes and concentrated on selection of icon and simple text to represent the concept of HIE.

The sample size of five persons was appropriate with regards to patient time constraints, researcher availability, and the variability of the patient population (Hertzog, 2008).

A prototype with four icon examples for each consent stage was used to stimulate discussion (Figure 13). Icons were initially chosen by the researcher after viewing recommended clip art links on the Sage Bionetworks website (Sage Bionetworks, 2015a, 2015b). Icons were selected from clip art to represent concepts related to technology regarding HIE (Figure 13). Icons selected were matched with simplified text headings (e.g., “What is HIE?” or “How is my information protected?”) to ascertain if the icon and simple text heading were a comprehensible, descriptive match that clearly walked patients through the HIE consent process electronically.

The headings used for the simple text were structured according to the U.S. Department of Health and Human Services (DHHS) and the Office of the National Coordinator (ONC) eConsent Video Trial Project (DHHS & ONC, 2013). The DHHS/ONC study presented a narrative in video format as educational material about HIE. After every screen’s title is presented (e.g., “What is HIE?”), the narrative would define the topic (DHHS & ONC, 2013). In the DHHS/ONC study, it meant defining HIE. All scripts used for the topic narratives were reviewed for readability by the ONC, the Office of General Counsel, and the Office for Civil Rights prior to DHHS approval (DHHS & ONC, 2013). With the intent of improving consistency in language and incorporating the necessary legal clauses, this resulted in unintended higher readability levels (DHHS & ONC, 2013). Thus for this dissertation study, only the headings were directly used for the eConsent app prototype, and the text was simplified to lower the readability level.

Participants were asked to select icons that best represented a set of questions and to describe their rationale for the selection. The questions were as follows:

- What is HIE?
- What health information can be accessed?
- Who can access my information?
- How is my information protected?
- What are my choices for consent?

All interview data were audio recorded and subsequently de-identified. The selected icons were documented, and once analyzed, they were uploaded and used on the iPad eConsent. Data were stored in an encrypted network drive as per CUMC policy.

Analysis

Five participant icon selection interviews were transcribed by the researcher, and responses to the chosen icons and selected quotes about the rationale for selecting a specific icon or ideas about a similar topic were noted. These data were also used to provide context on how to improve the design of the eConsent. When a specific question garnered an equal number for more than one icon, such as in a tie, a decision was reached by using the participant’s rationale for selecting the specific icon. If the decision for a specific icon remained unclear, the researcher selected the icon that in her judgment best represented the interview question conceptually.

Figure 13. Illustration of Patient Icon and Simple Text Interview –Icon examples.

Questionnaire used for icon semi-structured interviews

Columbia University Medical Center

eConsent

Patient Icon and Simple Text Interview – Icon Examples

(Participants will provide their feedback to the Icons, but this is an example of what we will start with)

We will present this to participants during the focus group to better understand which icons best explain HIE. The eConsent is meant to walk participants through the consent process as structured in the bullet points below. This is an example and may change based on participant preference.

To be used with Question # 1 during the Icon and Simple Text Focus Group:
(Present Icon Examples to be used for the eConsent):

1. **What is HIE? (Which, if any, best describes a person thinking about the definition of HIE?)**




2. **What health information can be accessed? (Which, if any, best describes this?)**




3. **Who can access my information? (Which, if any, best describes this?)**




4. **How is my information protected? (Which, if any, best describes this?)**




5. **What are my choices for consent? (Which, if any, best describes this?)**




Results

Icon semi-structured interviews

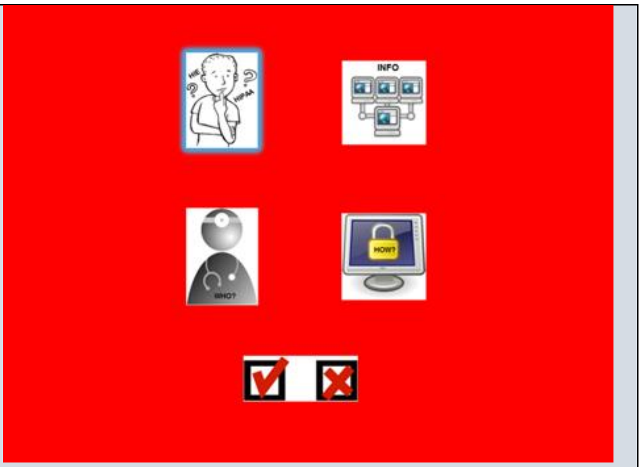
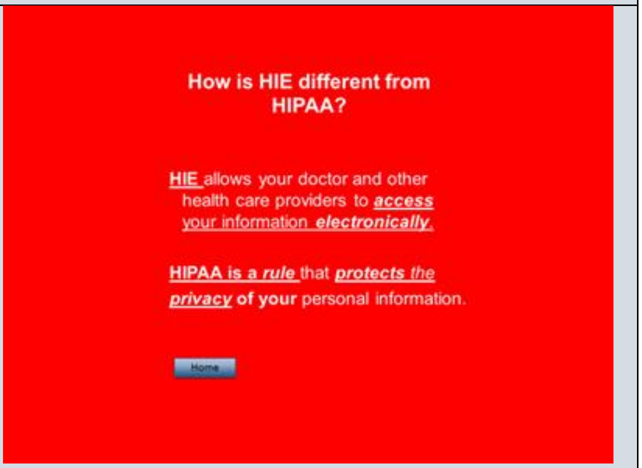
In response to the icon semi-structured interview questions (Appendix B), 80% selected the same icon that represented “What is HIE?” For the second question, there was a tie regarding “What health information can be accessed?” Two participants selected the icons that had multiple screens that appeared to be ‘communicating.’ Another two participants selected a cloud appearing to download/upload data, and one participant selected an icon of an electronic tablet. The researcher then selected the icon was the best conceptual representation of health information being accessed, which was the multiple computers that were ‘communicating.’ In question three, 60% of participants selected the same icon representing “Who can access my information?” The fourth question yielded a unanimous selection of the icon that represented “How is my information protected?” Lastly, 60% of participants selected the same icon that represented “What are my choices for consent?”

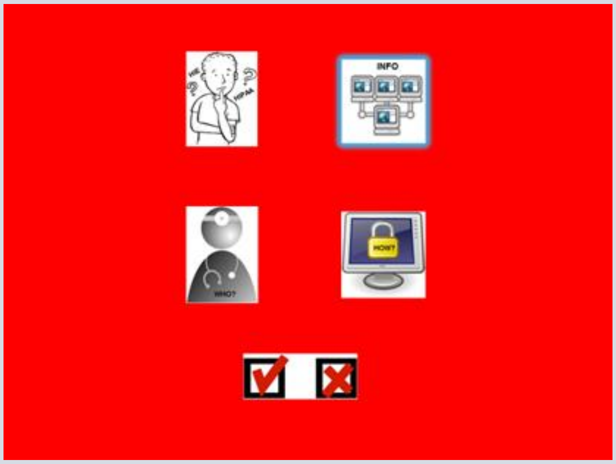
eConsent prototype development based upon results

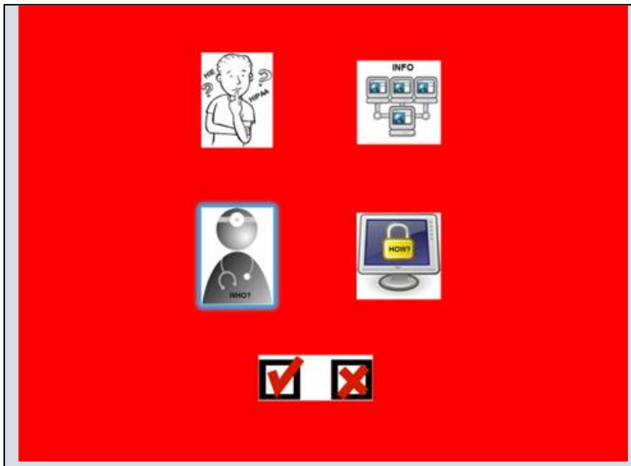
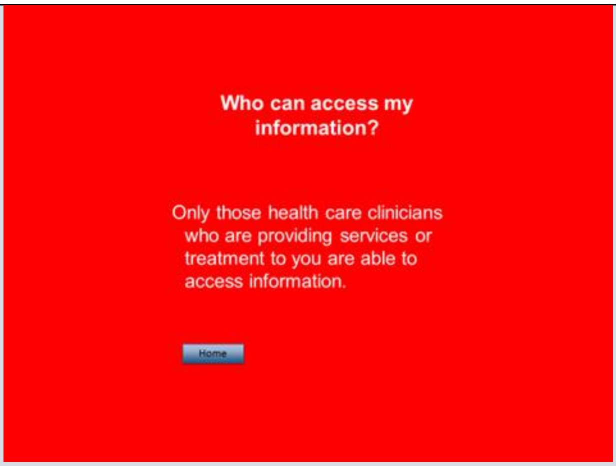
Four iterations of the eConsent prototype were created with the icons selected from the participant interviews. All eConsent prototypes were created using Microsoft PowerPoint to simulate app functionality. The researcher presented the prototype versions to a nurse scientist experienced in user interface design and changed the prototypes based upon her feedback.

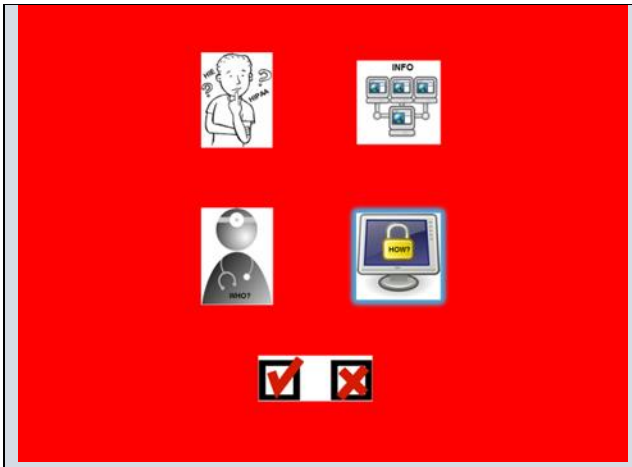
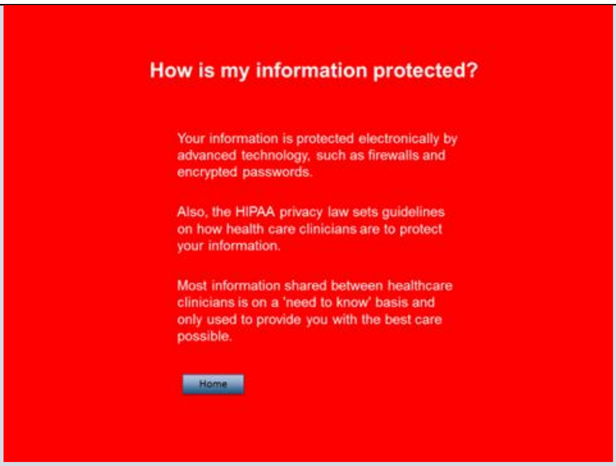
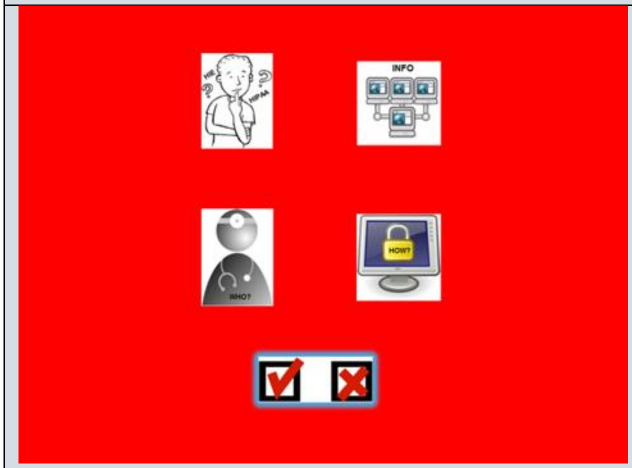
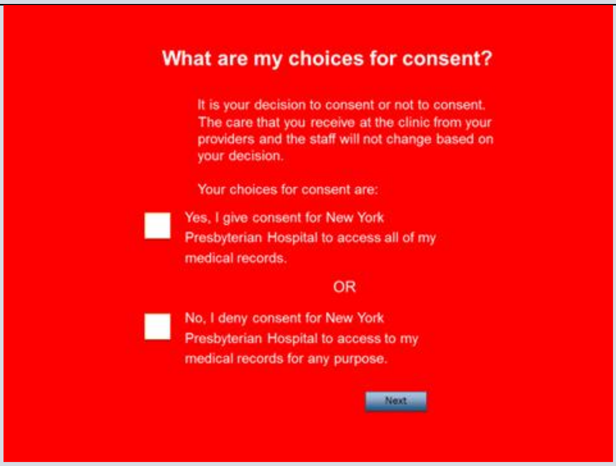
The final eConsent iteration included 16 screens, a five-icon home page, and highlighted icons that acted as a reminder to guide the user through the eConsent. Additionally, instead of the user self-navigating back to the home page, PowerPoint’s animation and transition features were used to automatically guide the user from icon to simple text and then back to the homepage. This prevented accidental navigation away from the content and prevented advancing to other content out of order. The final eConsent prototype is displayed in Figure 14 and was piloted with the twenty clinic patients as part of the final study phase (Figure 15).

Figure 14. Illustrative screenshots of the iPad eConsent HIE App.

 **Health Information Exchange Interactive eConsent** **NewYork-Presbyterian Hospital** **HP6** Protocol Number: AAAL3251 Columbia University Medical Center Institutional Review Board Introduction page. The user taps the green button to begin.	 Home page. The user taps the illuminated icon to answer the question: What is HIE?
 **What is HIE?** HIE allows your healthcare clinicians to view your medical records electronically from all places you received care, such as clinics, hospitals, emergency rooms and other facilities that are not affiliated with your primary care organization. The user reads the simple text in response to icon 1: What is HIE? And taps the illuminated "Next" button to continue to the next page.	 **How is HIE different from HIPAA?** **HIE** allows your doctor and other health care providers to ***access*** your information ***electronically.*** **HIPAA is a *rule*** that ***protects** the* ***privacy*** **of your** personal information. The user continues to read the simple text in response to icon 1: What is HIE? And taps the illuminated "Home" button to return to the homepage.

 Homepage. The user taps the illuminated icon to answer the question: What health information can be accessed?	 **What health information can be accessed?** All personal health information that is electronically available from other health care facilities where you received care can be accessed by NewYork-Presbyterian Hospital. • Doctors notes • Lab results • X-rays • Emergency room visits • Alcohol or drug treatment • Birth control • STD results • Mental Health Conditions • HIV / AIDS The user reads the simple text in response to icon 2: What health information can be accessed? And taps the illuminated “Home” button to return to the homepage.

 Homepage. The user taps the illuminated icon to answer the question: Who can access my information?	 **Who can access my information?** Only those health care clinicians who are providing services or treatment to you are able to access information. The user reads the simple text in response to icon 3: Who can access my information? And taps the illuminated “Home” button to return to the homepage.

 Homepage. The user taps the illuminated icon to answer the question: How is my information protected?	 How is my information protected? Your information is protected electronically by advanced technology, such as firewalls and encrypted passwords. Also, the HIPAA privacy law sets guidelines on how health care clinicians are to protect your information. Most information shared between healthcare clinicians is on a 'need to know' basis and only used to provide you with the best care possible. The user reads the simple text in response to icon 4: How is my information protected? And taps the illuminated "Home" button to return to the homepage.
 Homepage. The user taps the illuminated icon to answer the question: What are my choices for consent?	 What are my choices for consent? It is your decision to consent or not to consent. The care that you receive at the clinic from your providers and the staff will not change based on your decision. Your choices for consent are: ☐ Yes, I give consent for New York Presbyterian Hospital to access all of my medical records. OR ☐ No, I deny consent for New York Presbyterian Hospital to access to my medical records for any purpose. The user reads the simple text in response to icon 5: What are my choices for consent? And taps the illuminated "Next" button to continue to the next page.

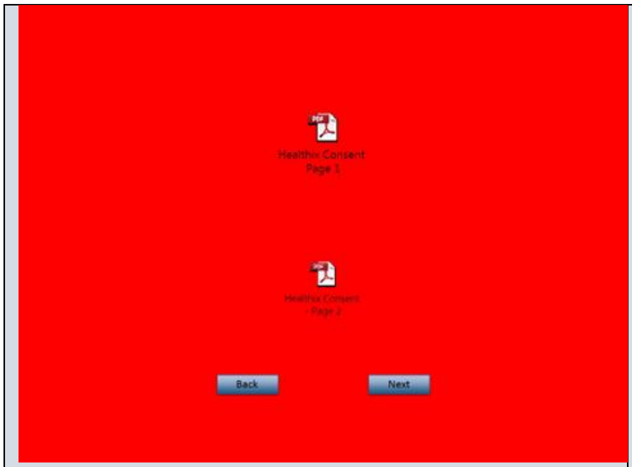
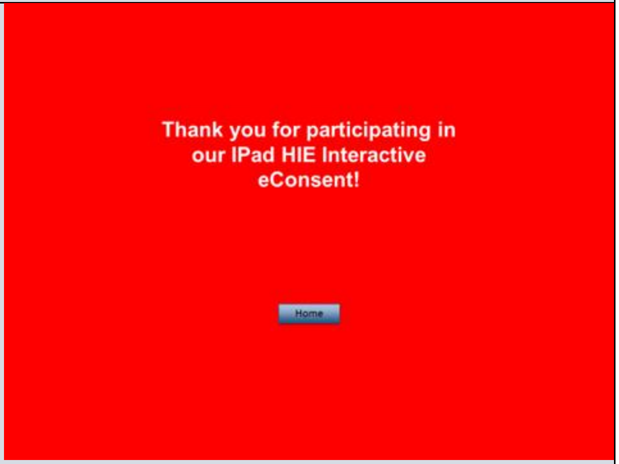
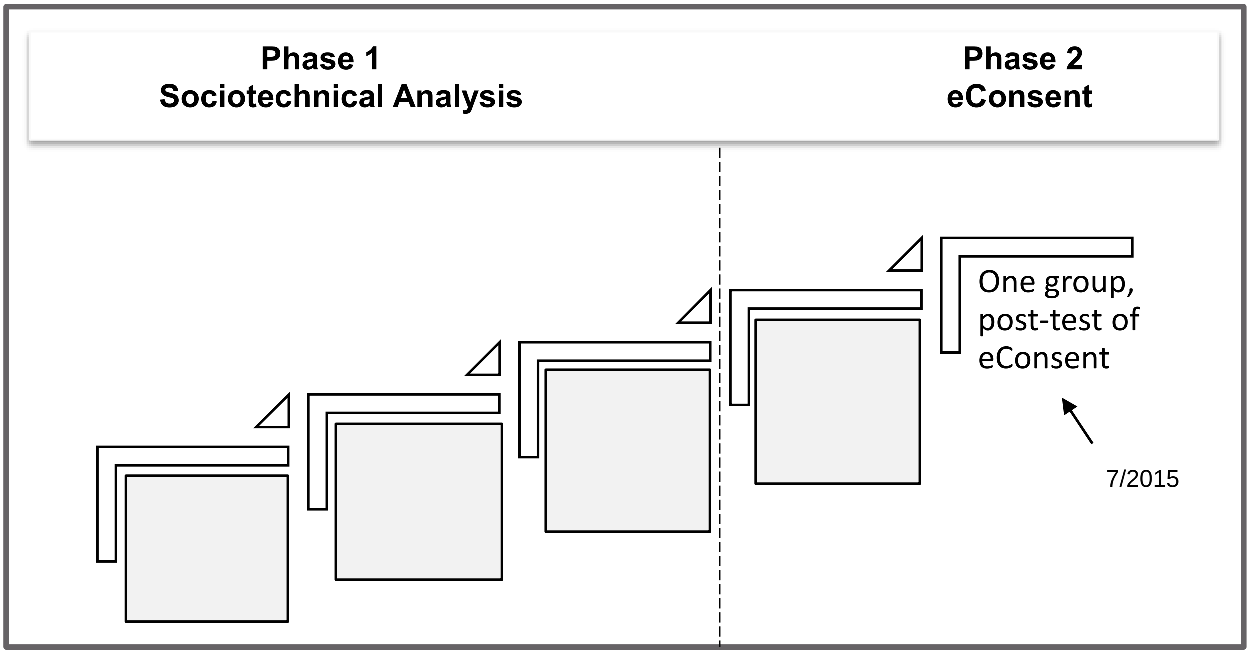
	
The user continues to read the simple text in response to icon 5: What are my choices for consent? And taps the illuminated "Next" button to continue to the next page or the illuminated "Back" button to review.	The user continues to read page 1 of the pdf generated clinic HIE consent in response to icon 5: What are my choices for consent? And taps the illuminated "Tap to Continue" button to continue to the next page.
	Thank you for participating in our IPad HIE Interactive eConsent!
The user continues to read page 2 of the pdf generated clinic HIE consent in response to icon 5: What are my choices for consent? And taps the illuminated "Tap to Continue" button to continue to the next page.	Final page. The user may stop here or tap the illuminated "Home" button to return to the homepage.

Figure 15. Illustration of Phase 2 / Aim 3



AIM 3: **To examine PLWH perceptions of the usefulness and ease of use of an eConsent for HIE, the preferences for eConsent when compared to the clinic's hardcopy consent, and comprehension of HIE concepts**

Testing the Electronic Consent

Aim III: To examine PLWH perceptions of the usefulness and ease of use of an eConsent for HIE, their preferences for eConsent as compared to paper consent, and comprehension of HIE concepts.

Research Design

The study conducted was a one group post-test design with participants randomized to either read the eConsent or paper consent first. Post-test measurements were comprised of a questionnaire and semi-structured interviews to test comprehension of HIE after both consent formats were administered. This was considered an appropriate design for several reasons. First, the primary purpose of this pilot study was to examine PLWH's perceptions of the usefulness, ease of use, and preferences of an eConsent when compared to the clinic's paper consent rather than to compare differences in comprehension between the two versions. Second, the rationale for not having a pre-test was the low variability of pretest knowledge about HIE in the population. Thus, a decision was made to not burden the participants with a pre-test measure.

Methods

Setting

The study was conducted at an urban, academic, medical center's HIV clinic which serves approximately 1700 patients. This clinic is part of the ambulatory care network (ACN) that provides HIV care to patients receiving federal (Medicare or AIDS Drug Assistance Program [ADAP]) or state (Medicaid) insurance.

Sample

The sample consisted of 20 current HIV clinic patients. Inclusion criteria for participants were the following: (1) not participated in the eConsent design process, (2) currently receiving care at the clinic, (3) English speaking, (4) English-language literate, and (4) willing to participate. For the purposes of this study, English-language literacy refers to the ability to read at minimum words with three syllables and sentences with at least 10 words (Doak et al., 1996). The ability to read this study's information sheet and agree to participate demonstrated the appropriate level of literacy. Exclusion criteria were as follows: (1) severe visual impairment, (2) inability to read English, and (3) inability to communicate in English in order to verbally consent to participate in the research study after reviewing the information sheet.

Recruitment

Following IRB approval as described for creating the eConsent prototype, participants were recruited using various strategies. First, flyers containing study information with a contact number was posted in the clinic common area. Interested prospective participants contacted the study's confidential voicemail system and were called back by the researcher. Second, the researcher recruited patients directly from the clinic's common area. Third, snowball sampling resulted from the study participants informing other clinic patients about the study in the clinic's waiting area. Those who met the inclusion criteria completed the intervention in a private room in the clinic's administrative area to ensure a quiet and comfortable environment. Data collection occurred over a four-day period for approximately eight hours per day during normal clinic hours.

Procedures

All participants (N=20) were randomly assigned to the consent format (eConsent or paper) that they would complete first. This was done using the Random Number Generator app's "coin toss" feature on an Apple iPhone. Prior to the coin toss app, it was determined that "heads = paper consent" and "tails = eConsent." Participants would then switch to the alternate consent format that they were not initially assigned. The iPad eConsent app prototype is an interactive application composed of one home screen with five icons that led to simple text describing the essential components of HIE. The app was designed to facilitate a better understanding of HIE through the use of icons, colored backgrounds, simple wording, and a touch screen (Friend, 2015; Mayer, 2009; Ritter, 2015; Wilbanks, 2014). This was intended to guide the reader step-by-step using multiple visual formats (Friend, 2015; Mayer, 2009; Ritter, 2015; Wilbanks, 2014). Once participants completed both the HIE eConsent and the paper consent, they completed a 4-question Likert-scale survey and a semi-structured interview that assessed their HIE comprehension using open-ended questions. Each visit took approximately 30 minutes to complete, and participants were given a $30 gift card for their time.

Study measures

First, all participants completed a demographic survey (Appendix C) that included information on age, gender, race, ethnicity, duration of living with HIV, and usage and comfort using the internet (Whiddett et al., 2006). Next, a 4-question Likert-scale (strongly agree to strongly disagree) survey was completed after participants completed the eConsent (Appendix D). The Technology Acceptance Model (Davis Jr, 1986) guided the creation of the survey items, which were as follows: (1) The icons let me know what content would be displayed when I clicked them, (2) The text under each icon was easy to understand, (3) The icons and simple text prepared me to read the legal HIE consent document, and (4) The electronic HIE consent app was easy to use. Lastly after participants completed reading both the paper consent and eConsent, semi-structured interviews were conducted to assess HIE comprehension (Appendix E). Open-ended questions explored the following areas: (1) comprehension of HIE by defining it in their own words, (2) perceptions about the paper version in comparison to the electronic version, and (3) preferred format.

Analysis

Quantitative analysis

Statistical Package for the Social Sciences (SPSS) version 23 was used during the data analysis process. Data were analyzed in the following sequence: (1) preparation of a codebook, (2) data entry from the questionnaires and interviews, (3) review of the data for errors, and (4) analysis of the results using descriptive statistics (Pallant, 2010). Sample characteristics were summarized using descriptive statistics (proportions, means, and standard deviations), and Likert-scale data was analyzed for frequencies. In addition, responses to the qualitative interview data were analyzed for frequencies by creating a data file and documenting the recorded response to which consent format (paper or iPad eConsent) was most preferred by the participant.

Qualitative analysis

Semi-structured interviews were audio recorded and transcribed by the researcher. The researcher transcribed the interviews while listening to the audio recordings. A thematic analysis was used for all 20 interviews to assess if the clinic participants were able to better comprehend HIE and which format for delivering consent information (paper or iPad eConsent) was preferred and why. The TAM (Davis Jr, 1986), which guided the Likert-scale items, also guided the open-ended questions for participant responses on ‘perceived usefulness’ and ‘ease of use’ regarding the eConsent. It was also important to capture the number of participants who were able to articulate the components of HIE (e.g., electronic access, all protected health information being shared, different from HIPAA, etc.). Themes or ideas about a similar topic that provided context on how to improve the design of the eConsent were also categorized and noted in the researcher notes.

The validity of qualitative research is measured through credibility, transferability, dependability, and confirmability (Lincoln & Guba, 1985). Credibility refers to the truth of the findings and can be measured by prolonged engagement, member checking, observation, and peer debriefing (Lincoln & Guba, 1985). In this study, engagement was demonstrated by the three year relationship that the researcher maintained with the clinic population. During those three years, the researcher recruited participants and led both focus group and semi-structured interviews. Throughout this time, familiarity and rapport between the researcher and participants was cultivated. Member checking occurred during the interviews by intermittently summarizing the participants' responses to ensure the accuracy of the researcher's understanding of those responses.

Transferability facilitates the application of context relevant information by gathering robust data (Speziale, Streubert, & Carpenter, 2011). Although this study was limited to one HIV clinic, the data obtained can potentially have meaning and applicability to other similar contexts that seek to explore how user-centric design and technology may facilitate comprehension of complex information.

Dependability and confirmability of results is based on replication of the study procedures that results in similar conclusions (Speziale et al., 2011). In this study, an audit trail was created through the researcher's notes gathered during the semi-structured interviews and study procedure documents. If replicated, the study procedures should yield similar outcomes using a similar sample of participants. This study's participants are of diverse demographic backgrounds, which added to the richness of the data.

Results

Participant characteristics

The participants (N=20) (Table 9) had a mean age of 54.6 (SD=10.8) with an age range of 33 to 69 years of age. Males comprised 75% (n=15) of the sample, and 55% of the participants (n=11) identified as African American. Seventy-five percent of the sample (n=15) were U.S. born, and 40% (n=8) were of Hispanic/Latino descent. Highest educational level included 20% (n=4) as having some high school but no diploma and 10% (n=2) as having a high school diploma/GED. Fifty percent had a two year college degree or greater. Forty percent of participants (n=8) had an annual salary of $10,000 or less. Forty-five percent (n=9) were enrolled in both Medicaid and Medicare. In addition, although not shown in the table, 30% (n= 6) of participants reported having never used the internet, and 65% (n=13) had HIV for greater than 10 years.

Table 9

Sample Characteristics.

Characteristics (N=20)	**n**	**%**
Gender		
Male	15	75
Female	5	25
Nativity Status		
U.S. born	15	75
Non U.S. born	5	25
Ethnicity		
Non-Hispanic	12	60
Hispanic/Latino	8	40
Race		
White	3	15
African American	11	55
Multi-racial	1	5
Other	5	25
Sexual Orientation		
Heterosexual	9	45
Bisexual	2	10
Gay or Lesbian	8	40
Unsure	1	5
Education		
Some high school no diploma	4	20
High school diploma / GED	2	10
Some college / no degree	3	15
Trade / vocational school	1	5
Associate degree	3	15
Bachelor degree	6	30
Graduate or professional degree	1	5
Income		
No income	1	5
Between $5 - $10K	7	35
Between $10,001 - $20K	4	20
Between $20,001 - $30K	3	15
Between $30,001 - $40K	3	15
More than $40,000	1	5
Medical Coverage		
Medicare	3	15
Medicaid	5	25
Medicaid & Medicare	9	45
Ryan White	1	5
Private/Other	2	10
Age		
Mean 54.60 (SD 10.8)		

Comprehension

Semi-structured interviews

Thirty-five percent of participants (n=7) verbalized more than one essential component of HIE in their responses (i.e., high level of comprehension), such as the following: (a) all PHI being shared electronically, (b) HIE being different from HIPAA, (c) HIE being accessible at various hospitals, clinics, emergency departments, and (d) a person must sign a written consent in order to share. The education level of those PLWH with high comprehension included: two with some college but no degree, one with a trade degree, one with an associate degree, two with bachelor degrees, and one with a graduate degree. Listed below are selected quotes from those that demonstrated comprehension by verbalizing more than one component of HIE (Appendix F):

> *"It's an exchange of health providers of all places you've been treated so it's your entire medical history where ever you are."- Participant 1*
>
> *"It's a program where your medical doctors have access to your medical records whether it's at the clinic or outside of the hospital and lists the health conditions that I have and what treatments I have gotten. You must sign a consent form to have the doctors' access my information."- Participant 7*
>
> *"Essentially allows healthcare providers to access your information at what hospital, clinic or doctor you may be working with. So it sorta connects everybody."- Participant 9*
>
> *"From what I understand it's supposed to be the Healthix.. I believe it so the doctors that are giving you medical care can keep a connection and directly correspond with each other to know what to do and know your care to treat you better."- Participant 10*
>
> *"Health information exchange, it provides electronic access to treatment providers. This can be anywhere that the HIE exists." – Participant 12*
>
> *"It's a way for other medical institutions to access my health information electronically without having to make all of these crazy calls or faxes. If I ended up at Beakman downtown they would be able to access."- Participant 14*
>
> *"It's about the whole process of how if I were injured another hospital my doctors can always check back on the information from the other hospital. They can always access what was done what was administered to me if I was outside of my healthcare circle." – Participant 20*

Twenty percent of participants (n=4) were able to verbalize one essential component of HIE in their responses when asked. The education level of those PLWH with moderate comprehension included: one with some college but no degree, two with an associate degree, and one with a bachelor degree. Examples of their responses are as follows:

> *"I would be consenting to RHIO which basically information would be given to clinics and doctors and only healthcare providers would be able to see the information." –Participant 3*
>
> *"Easier way to access your information, especially if you're not in a way to coherently speak for yourself."- Participant 4*
>
> *"It provides electronic information to the clinic you go to. To the doctors that takes care of you. Can understand more of what they're dealing with."- Participant 6*
>
> *"A system for putting together and providing access to health records of patients." – Participant 8*

Forty-five percent participants (n=9) were unable to verbalize any essential components of HIE in their comprehension interview responses when asked. The education level of those PLWH with no comprehension included: four with some high school experience but no diploma, two with a high school diploma/GED, and three with a bachelor degree. Selected quotes include the following:

> *"It's about my status my sickness, my medications and my doctors." – Participant 2*
>
> *"HIE is when you have privacy. The way I understood it.. when you have privacy in the facility where you receive the medical care and you decide you want medical care elsewhere you would get a consent." – Participant 11*
>
> *"It's about your health, your HIV status, your TCells and uh viral and TCells. It tells you about your health. What meds to take. Helps you stay healthy with your HIV status." – Participant 13*
>
> *"HIE it's not HIV? HIE its more less the… What's HIE?" – Participant 17*
>
> *"It's about the research with the HIV thing." - Participant 19*

Preferred Consent Format

With regards to the paper and iPad eConsent assignment, 75% (n=15) were initially assigned to read the paper consent, and the remainder used the eConsent first. Over half of the participants (n=14) were in favor of using the iPad eConsent over the paper consent. Those favoring eConsent included: two with some high school but no diploma, two with a high school diploma/GED, three with some college but no degree, one with a vocational/technical diploma, three with an associate degree, and three with a bachelor degree. Selected quotes from participants in response to the eConsent are as follows (Appendix G):

> *"It [eConsent] was less intimidating and more to the point. Less is more and this was more. This delivers more in less time and is not as intimidating [as a paper consent]. Since we live in an age of technology, people are just more familiar with it and even people that aren't are going to find it [eConsent] easier." – Participant 4*
>
> *"I like the iPad. It's more concise. It's straight to the point. The paper version is stretched out. It's longer… it's a deterrent to a lot of people too. Especially if their reading capability is not… well attention span is… so that can be a real hindrance. A lot of people are gonna gravitate towards that [eConsent] because if you're not a reader, you'll be very despondent."- Participant 5*
>
> *"The paper version is kind of long… too many words.. I read everything but some people will not be reading it. I was so simple. It tells you what it is. It gives you the important things first and I understood it perfectly."- Participant 6*
>
> *"It [paper version] was a lot of information to remember and understand, the type was small and there was a lot of information so it took a lot of time to read it all. I'm not sure that I read every word so it's sorta cumbersome. Certainly more entertaining [the eConsent] if just for the colors used. It's hard to believe that it had all that information on it. It seemed so accessible. The electronic was easier and more inviting. More easy to read."- Participant 8*
>
> *"Honestly, I would never read this much information. Um, if I see it I would just sign it – yeah that's too many words for me right there. I generally do not read those types of things. I think the electronic version is simple to use. I would read that because they're more simple, concise paragraphs. I guess more interactive and I'm used to that. All of the information is essentially given. I use the computer. I have an iPad and all that so um to me it's very convenient and it's less paper to deal with. I prefer electronic because I think that's where most things in life are going in general."- Participant 9*

Thirty percent of the participants (n=6) preferred using a paper consent instead of an eConsent. Those favoring paper consent included: two with some high school but no diploma, three with a bachelor degree, and one with a graduate degree. Selected quotes are as follows:

> *"It [paper consent] was very understanding. It [eConsent] is also understanding. I like it. But, I'd pick the paper because I could take my time reading it."- Participant 13*
>
> *"It's very good [paper consent]. It tells everything about the consent very well. In today's world, the paper stuff is not being used. It's all about the computer. "[Participant preferred] The paper I can keep it and see it." – Participant 15*
>
> *"I think the paper version explains it better because it gives you the words instead of just the icon. You have a better understanding with the words. The electronic is good. I guess I would do better with the paper*

> *because I'm used to it. The electronic is easy but I'm used to paper even though it is more tedious."- Participant 18*

Perceived Usefulness and Ease of Use of eConsent

Survey results suggested that 65% of participants (n=13) agreed or strongly agreed that the icons informed them of upcoming eConsent content. Ninety percent (n=18) reported (agreed or strongly agreed) that the text represented by each icon was easy to understand. More than half of the participants (70%) reported that they strongly agreed the eConsent icons prepared them to read the HIE consent pdf document on the iPad. Eighty-five percent (n=17) reported that they strongly agreed the eConsent was easy to use.

Consent Preference Based Upon HIE Comprehension Assessment

Triangulated interview and survey data (Table 10) suggested that the majority of those who demonstrated high or low levels of comprehension and all who demonstrated a moderate level of comprehension preferred the eConsent. Four of six who preferred the paper consent demonstrated low comprehension of HIE.

Table 10

Illustration of triangulated responses to consent preference by level of comprehension.

	# that preferred eConsent	**# that preferred paper HIE consent**	**Selected Quotes**
[1]High level of comprehension	5	2	"Honestly, I would never read this much information. Um, if I see it I would just sign it – yeah that's too many words for me right there. I generally do not read those types of things. I think the electronic version is simple to use. I would read that because they're more simple, concise paragraphs. I guess more interactive and I'm used to that. All of the information is essentially given. I use the computer. I have an iPad and all that so um to me it's very convenient and it's less paper to deal with. I prefer electronic because I think that's where most things in life are going in general." [preferred eConsent] The iPad was easier to read. I would want it blown up a little more [the words] but it was fine. I grew up reading 3 papers a day. It's nice to have the electronic. Growing up we never had computers or phones….so I still prefer paper. [preferred paper consent]
[2]Moderate level of comprehension	4	0	"It [eConsent] was less intimidating and more to the point. Less is more and this was more. [preferred eConsent] This delivers more in less time and is not as intimidating [as a paper consent]. Since we live in an age of technology, people are just more familiar with it and even people that aren't are going to find it [eConsent] easier." [preferred eConsent]
[3]Low level of comprehension	5	4	"It [paper consent] was more confusing but I got to know where I stand. "It [eConsent] helped me out in a way to understand what was going on. For me, the words I didn't really understand how to read it, but I felt like I needed help and some words I didn't know, you know? Even though I was doing it on a computer, I would really do it on a paper. The paper helped me sound the words out." In some ways I understand and some ways I didn't [the eConsent]." [preferred paper consent] "I was surprised because of the difference [paper consent]. I like the electronic version because sometimes they ask you and you don't have to go through those stages. It was simpler." [preferred eConsent]

[1] High comprehension = ability to report one or more essential component of HIE
[2] Moderate comprehension = ability to report one essential component of HIE
[3] Low comprehension = unable to report any essential component of HIE

Discussion

Implications for improvement of the user-centric eConsent

This study utilized a user-centric approach in the design of the eConsent (Årsand & Demiris, 2008). Clinic patients provided feedback on which icons they perceived best visually represented the concepts of HIE. A three-tiered approach using icons, simple text, and a generated pdf was the initiative of John Wilbanks at Sage Biometrics (Sage Bionetworks, 2015b). This initiative resulted in the Patient-centered Consent Toolkit (Sage Bionetworks, 2015b), which guided this dissertation study's HIE eConsent design.

Because there is no one standard model that facilitates comprehension of consent documents, this study used approaches from a variety of frameworks to best meet the needs of this HIV clinic's diverse population. Icons were used as part of the three-tiered approach (Sage Bionetworks, 2015b). The concept of simple text was used from the three-tiered approach, but simple text from an eConsent video study (DHHS & ONC, 2013) guided the wording for the application. The principles of coherence, signaling, multimedia and personalization (Mayer, 2009) supported the eConsent design. Recognition heuristics supported the eConsent's low cognitive effort during navigation of the app (Goldstein & Gigerenzer, 1999). Aggregating these frameworks was a novel approach in the overall eConsent design, as all were complementary.

The qualitative eConsent comprehension testing yielded three participant rankings: (1) those that were able to verbalize more than one component of HIE, (2) those that were able to verbalize one component of HIE, and (3) those that were not able to verbalize any components of HIE. Despite incorporating simplified text and content, the study findings suggested that after completion of both consent formats, there was still confusion and a lack of understanding about HIE. Interestingly, of the participants that were unable to demonstrate comprehension, five out of nine participants preferred the eConsent, while four out of nine preferred the paper consent. Although small changes to simplify wording may improve understanding (Jadad & Enkin, 2008), it is uncertain if this would be beneficial, given that there was no meaningful difference in the number of those with low comprehension that preferred one format over the other (Table 10).

The majority of study participants were ethnic or racial minorities, of which more than half had some college with no degree or greater. This does not support the varying comprehension testing results, as most were college educated and almost half of the participants had some high school experience or high school diplomas. This finding indicates that factors other than educational achievement, such as social, economic, psychological, and linguistic factors may contribute to lower levels of comprehension and ability to be informed (Jadad & Enkin, 2008). Moreover, HIE is a complex construct and health literacy does not necessarily align with overall functional literacy. Other studies with similar participant characteristics suggested that having minority status and having an annual income of less than $15,000 (Patel et al., 2011) were identified as being negatively associated to electronically sharing PHI when compared to non-minorities and those with higher annual incomes (Wen, Kreps, Zhu, & Miller, 2010). Thus, the inability to comprehend information may decrease informed decision making, which may be a key factor for HIV clinic patients and their ability to make an informed decision about HIE consent.

More than half of the study participants had college education, but there was still some difficulty with understanding the essential components of HIE. Of those that were college educated (i.e., having some college training with no degree, having an associate, bachelor or graduate degree), 35% verbalized more than one essential component of HIE and 20% were able to verbalize one component of HIE when asked. The majority of those that were not able to verbalize any components of HIE included four persons with some high school with no diploma, two high school graduates, and three persons with a bachelor degree. This suggests that a user interface, such as the eConsent, is not adequate as an independent means to facilitating comprehension. In addition to the eConsent, human interaction may be needed to better address the complexities of HIE-related information alongside supplemental multimedia interaction.

Currently, Food and Drug Administration guidelines suggest that consent wording should not exceed an eighth-grade reading level (Alper, 2015), and Doak and colleagues (1996) suggest that literature is most appropriate when it is written at the fifth-grade level (Doak et al., 1996). Though legally required, paper consents provide weighty information that distracts individuals from having a clear explanation of study procedures (Kass, Chaisson, Taylor, & Lohse, 2011; Rothwell et al., 2014). Because of this, the feasibility of moving towards an easy to read, user-centric eConsent model remains a critical issue, yet there is no current standard of measuring if patients who have consented are fully informed. Since there is limited literature available on the issue of consent comprehension, further research is warranted on exploring the best approaches to facilitate the delivery of HIE consent using validated, comprehensible formats and user-centric techniques that incorporate knowledgeable, dedicated persons to assist PLWH in comprehending and consenting to HIE.

Chapter Five

Overall Discussion

This chapter summarizes (Table 11) and discusses the two phases of the dissertation. Phase 1 comprises Aim 1, which focused on the sociotechnical context of HIE for PLWH. Phase 2 includes Aim 2 and Aim 3, which addressed eConsent and its use in HIE consent. In addition, the strengths and limitations of the dissertation are provided, and the implications for research, practice, and policy are presented. Lastly, the overall conclusions are summarized.

Table 11

Summary of Phase 1 and Phase 2.

	Design	Sample	Methods	Results
Phase 1 Socio-technical Analysis	Secondary Data Analysis	(N= 291) HIV clinic patients	Logistic regression using the Bonferroni correction	Being U.S. born was a significant factor for PLWH sharing PHI with selected healthcare personnel.
	Descriptive, Observational	(N = 4) Registration Clerks	Observation workflow analysis and semi-structured interviews	Workflow analysis suggested multiple interruptions, competing demands, and high volume environment. Semi-structured interviews suggested that registration clerks are unfamiliar with the important components of HIE.
	Qualitative	(N = 19) 12 patients 3 patient navigators 4 clinicians	Semi-structured interviews and focus groups	Facilitators: Dedicated consent administrator Barriers: Confusion, lack of understanding, inability to distinguish HIE from HIPAA.
Phase 2 eConsent Design and Pilot Study	Mixed Methods	(N = 25) Clinic patients n=5 an icon focus group n=20 one group, post-test design with comprehension assessment	Focus group, post-test, semi-structured interviews	Icon focus group: The final eConsent iteration included 16 screens, a five-icon home page, and highlighted icons using PowerPoint’s animation and transition feature. eConsent pilot study: Across comprehension levels, most participants preferred the format of the eConsent when compared with the clinic’s paper consent. Only 11 out of 20 participants could identify one component of HIE.

Summary of Phase 1

Sociotechnical Analysis

Aim I: To explore the sociotechnical context of obtaining HIE consent in an HIV clinic.

Summary of the sociotechnical analysis in obtaining HIE consent in the context of an HIV clinic.

The sociotechnical context of HIE for PLWH is complex. There are many external and internal influences on the HIE consent process as well as multiple stakeholders. This complexity makes HIE difficult in HIV care despite the promise of benefits to quality of care, including continuity of care from diagnosis through treatment (Gardner et al., 2011).

In Phase 1, a sociotechnical analysis of the facilitators and barriers to HIE consent for PLWH was conducted. Multiple techniques were utilized that contributed to the richness of the study findings. An analysis of an existing dataset examined factors that influenced PLWH sharing of PHI. Registration clerks were observed, as they were responsible for discussing and obtaining HIE consent from the clinic patients. A flow chart and sequence model were created to illustrate areas of fragmented and interrupted workflow. Registration clerks were also interviewed to better understand their perceptions about barriers to HIE consent for the clinic patients. Patients, patient navigators, and HIV clinic clinicians were interviewed to ascertain their perceptions about the barriers to HIE consent.

Survey results suggested that PLWH are willing to electronically share their PHI. The results of the observations and interviews suggested that there are many interrelated, complex factors that affect HIE consent at the clinic. First, observations revealed that registration clerks have a fragmented workflow with multiple competing demands. They are unfamiliar with the important components of HIE, making it even more difficult to prioritize this task. Second, patients were confused about HIE. They were unclear about its distinction from HIPAA and were concerned about how consenting would affect the privacy of their HIV status. Patients were also unfamiliar with the clinic's paper consent form, and for many, it was the first time they had seen the clinic's paper consent. Third, patient navigators were identified by both patients and HIV clinic clinicians as trustworthy peers with the potential to play a role in HIE consent. However, patient navigators were also unclear about the concept of HIE and how it was facilitated at the clinic. Fourth, clinicians believed that patient care and patient education were greater priorities, such as reviewing CD4 and T-Cell counts. Lastly, non-standardized HIE processes add to the lack of clarity about how consent should be discussed and obtained. For example, there are states where written HIE consent is required and other states where an individual by default is "opted-in" to HIE. This study was conducted in NYS, which requires written consent to electronically share PHI in the HIE. However, there are no institutional initiatives or policies in place for standardizing the delivery of how HIE consent is discussed and obtained at the clinic.

Although the sociotechnical analysis revealed multiple potential targets for intervention, supporting the face-to-face process for requesting HIE consent was chosen as the initial intervention target for several reasons. First, decisions about workflow and who should request HIE consent were within the purview of the HIV clinic and not the researcher. Second, the release of the Apple Research Kit (Ritter, 2015) and research about layered approaches (Hermosilla, 2015; Ritter, 2015; Sage Bionetworks, 2015b) to eConsent provided the foundation for an approach to HIE eConsent in the HIV clinic due to its simplistic design and user-interface. Third, designing a prototype eConsent (Phase 2) and pilot testing it with a small sample of PLWH was a project with sufficient boundaries for completion as a dissertation study.

Significance of the sociotechnical analysis about obtaining HIE consent in the context of an HIV clinic.

Health information exchange supports the continuum of care, and the current NYS "opt-in" consent procedures present complex challenges in the HIE consent process. Based on a review of the literature, little was known about the factors that influence PLWH consent to HIE. By using mixed methods (e.g., secondary analysis of survey data, observation, semi-structured interviews and focus groups), the triangulated findings from the sociotechnical analysis suggested that there is no single solution to address HIE consent at this clinic because of the multiple challenges encountered by each key stakeholder. This finding adds to the knowledge about HIE in regard to PLWH, as this has not been previously reported in the literature. The findings in this study indicate that process changes in clinic procedures for discussing and obtaining HIE consent should incorporate user-centric approaches to best meet the complex and diverse comprehension needs of this population and to better streamline the HIE consent process. This could improve registration workflow and better facilitate the delivery of HIE consent related information in structured, clear, and logical ways. One example of this would be to address the clinic patient's inability to distinguish HIE from HIPAA by using alternative formats or strategies in addition to the paper consent form, since our focus group findings revealed that this was a major source of confusion for PLWH. As for workflow, having a dedicated person assigned to discuss and obtain HIE from patients may improve the number of those receive discussion about consenting to HIE.

Additional study findings from this study suggested that patient navigators are significant members of the HIV patient care team. Interventions to better facilitate HIE understanding for PLWH at this clinic should consider patient navigators as potential key persons to discuss and obtain HIE consent, which may also streamline the HIE consent process at this clinic. This concurs with current knowledge in the literature that dedicated personnel and one-on-one discussions are of value in improving understanding during informed consent (Flory & Emanuel, 2004). Patient navigators may address workflow barriers by acting as dedicated personnel and explaining the differences between HIE and HIPAA to the HIV clinic patients.

Furthermore, other studies about patients' perceptions towards electronically sharing their PHI had an overrepresentation of Caucasian respondents, and data were collected via a random digit dialer interview (Dimitropoulos et al., 2011; Patel et al., 2011; Weitzman et al., 2012; Whiddett et al., 2006). This is in contrast to this study's sample of typically underrepresented, racial and ethnic PLWH. This highlights and supports our review of the literature, which suggests that differences in participant characteristics, such as race, ethnicity, health literacy, and numeracy (Osborn et al., 2011; Osborn et al., 2007) are influential in the decision of PLWH to consent to electronically share PHI.

Currently, over half of the nation uses an "opt-out" consent or automatically in HIE by default (Gray, 2011). States such as Connecticut, Indiana, or Illinois do not require a written consent. Information is automatically accessible and transferrable using HIE. This dissertation study focused on "opt-in" consent for PLWH. Other studies have focused on HIE use for governmental, research, and public health purposes (Herwehe et al., 2012). This study highlights the importance of ascertaining the perceptions of consenting to electronically share via HIE for PLWH. Research from this study may be useful to provide insights for other chronic disease populations, such as those with diabetes or mental health issues. However, similar to HIV diagnosed individuals, those living with mental health issues or having documented medical history of abortions, mental and substance abuse may also have fear of stigmatization, mistrust, etc. and thus not be willing to share. Additionally, for those persons whose information is automatically shared through “opt-out” HIE consent, it would be advantageous to elucidate if they are aware that their PHI is being shared and if they too understand the implications of electronic sharing.

Summary of Phase 2

eConsent

Aim II: To apply a user-centric approach to design an HIE eConsent for PLWH at a HIV clinic.

Summary of the application of user-centric approaches in the design of an HIE consent for PLWH.

Multiple design frameworks were utilized in the iterative design of the eConsent. Patients were instrumental to the design, as their feedback informed which icons would be used in the eConsent app. Five semi-structured interviews were conducted using an icon prototype with four icon examples and simplified text headings for each consent stage.

Based on participant feedback during the icon selection interviews, the final iteration included 16 screens, a five-icon home page, and highlighted icons that were all created using Microsoft PowerPoint. Even though the sample size of participants interviewed about icon selection was small (n=5), it was still meaningful because the overall clinic patients’ characteristics were similar (Hertzog, 2008). Thus, the icons selected would be potentially more understandable to the study participants that completed the eConsent.

Significance of the application of user-centric approaches in the design of an HIE eConsent app for PLWH.

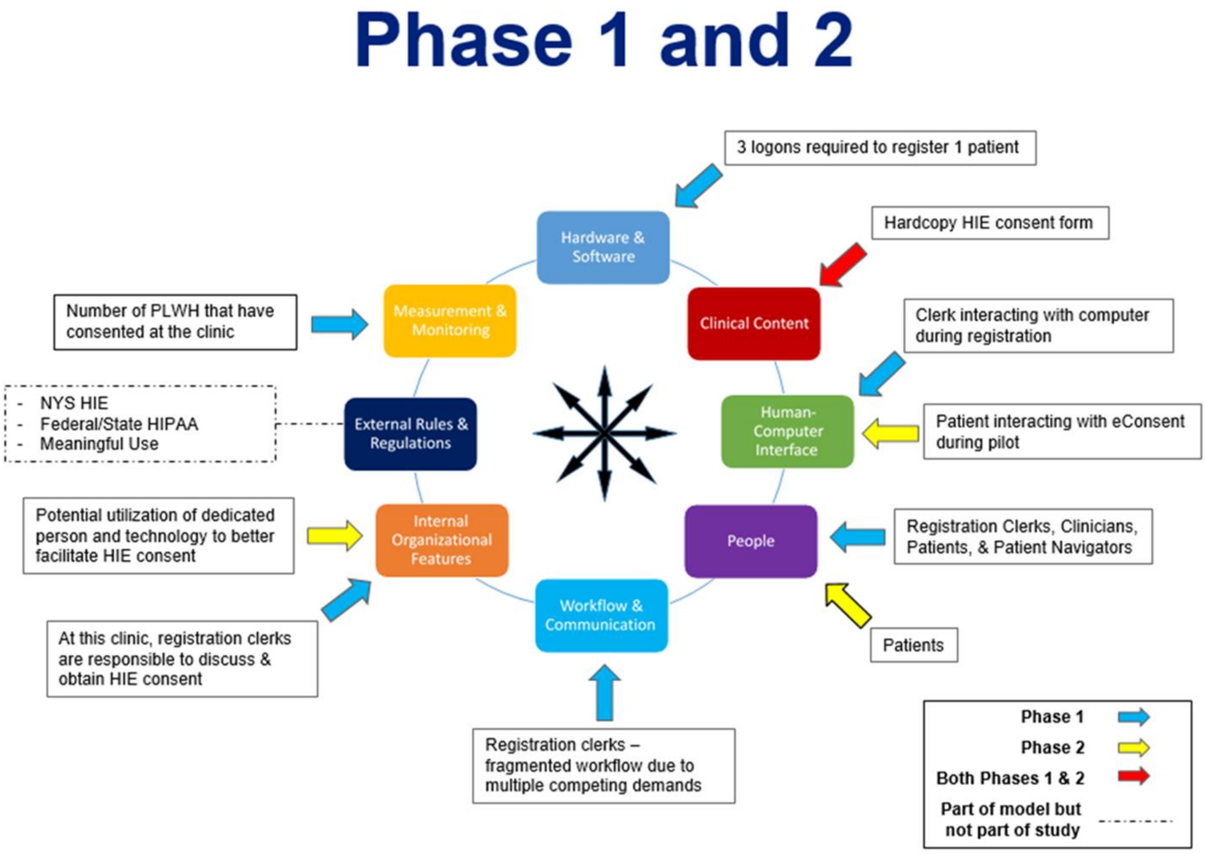
This was the first step in the user-centric design process. From this study, icons were selected that participants deemed were best representative of HIE consent concepts. This is a novel approach because the three-tiered layering process that starts with an icon has been used in electronic applications having to do with asthma, diabetes, and Parkinson’s disease (Hermosilla, 2015; Ritter, 2015; Sage Bionetworks, 2015b), but it has never been used in the context of HIE consent. This portion of the study has set the foundation and illustrated the importance of integrating patients into the early design stages of an HIE eConsent intervention. Interventions are most beneficial when they are tailored and guided by the needs of the end-user population, which in this instance is PLWH at the HIV clinic (Årsand & Demiris, 2008).

Aim III: To examine PLWH perceptions of the usefulness and ease of use of an eConsent for HIE, their preferences for eConsent as compared to paper consent, and comprehension of HIE concepts.

Summary of the eConsent pilot for PLWH at an HIV clinic.

Based on the review of the literature, which identified that innovative solutions are needed to reduce the barriers to HIE consent, and the findings from the sociotechnical analysis (Figure 16), a user-centric approach guided the design of an eConsent prototype app using an iPad (Årsand & Demiris, 2008). This was designed as a response to help PLWH make more informed decisions about consenting to electronically sharing their PHI. A one group, post-test only design examined usefulness and ease of use, using two constructs from the TAM. Semi-structured interviews assessed comprehension after both the eConsent and paper consent were read. Of all the participants, 85% believed that the eConsent was easy to use. However, 45% of the participants were unable to describe at least one component of HIE during the comprehension semi-structured interviews. Out of a population 20, four had some high school experience, two had a high school diploma/ GED, two had some college but no degree, one had a trade/vocational school diploma, three had an associate degree, six had a bachelor degree, and one had a graduate degree. This suggests that while considered to be easy to use and perceived as convenient (the study's conceptualization of perceived usefulness), the eConsent was not successful in achieving the goal of increasing comprehension of HIE consent despite the high percentage of the population that had college-level education. This finding was significant since multiple approaches were employed to design an eConsent that would be understandable to the diverse clinic population. Moving forward, more research is warranted on obtaining a better understanding of what components are needed to improve the design of multimedia to better convey HIE-related information and increase comprehension. The concepts of HIE are complex. Because these concepts are not integrated into daily conversations, broadcast media and newspaper publications, it may take time for an individual to understand the definition and implications of HIE regardless of educational attainment.

Figure 16. Illustration of the application of the Sociotechnical Model for Phases 1 and 2.



Significance of the eConsent pilot for PLWH at an HIV clinic

Flory (2004) suggested that one-on-one discussions would be the most effective strategy to facilitate understanding of information disclosed during informed consent (Flory & Emanuel, 2004). However, our findings suggest that comprehensive one-on-one discussions are difficult to systematically achieve in the HIV clinic because of the workflow challenges during the patient registration process. Consequently, alternative and complementary approaches are needed. Technology and informatics-based approaches have the potential to systematically support a user-centered approach to HIE consent for multiple reasons.

First, technology enables the use of multimedia which has been shown to improve comprehension (Palmer et al., 2011). The Cognitive Theory of Multimedia Learning is premised on the assumption that colors, words, graphics, listening and watching all contribute to an individual’s learning (Mayer, 2009). Because learning is activated by different channels in the brain, this theory integrates multiple principles that appeal to both auditory, tactile, and visual learning (Mayer, 2009; Mayer & Moreno, 2002). This may be a facilitator in improving comprehension of complex literature, such as HIE consent. Based on the results of participant comprehension and preference, more research is needed on how to improve comprehension using multimedia approaches that can reach many levels of understanding.

Second, technology facilitates a layered approach to information delivery in which the complexity of the information being presented increases as the user moves to deeper layers in the user interface. For example in this study, as part of the three-tiered approach (Meade & Howser, 1991; Ritter, 2015; Sage Bionetworks, 2015a, 2015b), users initially viewed an icon that led them to a simple text of information. This was meant to reduce cognitive effort about what information would be presented next (Goldstein & Gigerenzer, 1999). Once all of the information was presented using icons (layer 1) and simple text (layer 2), a full text copy of the paper consent was displayed on the iPad (layer 3). This layered approach complements Mayer's (2009) Cognitive Theory in that all steps appeal to the visual (seeing icons) and tactile (user interface with the iPad).

Third, a substantial theoretical base exists regarding the design of user interface to increase the likelihood that they are perceived as user-centered, i.e., easy to use and useful for their users (Schnall, Gordon, Camhi, & Bakken, 2011; Schnall, Odlum, Gordon, & Bakken, 2009). The applicability of the TAM (Davis Jr, 1986) to various studies to increase HIT-related interventions is another significant approach used in this study to measure ease of use and usefulness via interview data, respectively. In this study, the TAM was used to assess the participants' perceptions about the eConsent's perceived usefulness and ease of use. Perceived usefulness was identified as the participant's perception that eConsent was a more convenient facilitator of HIE consent than the paper consent. Perceived ease of use was identified as the participant's ability to navigate the eConsent intuitively and effortlessly. Of all the participants, 65% preferred the eConsent over the paper consent. Based on the responses from the comprehension interviews, the participants indicated that the eConsent format better presented HIE consent, which indicates a perception of usefulness for them. However, 45% of the participants were unable to describe one component of HIE during the comprehension semi-structured interviews. The participant interview findings and comprehension results suggested that PLWH have complex and diverse needs regarding comprehension and that legalese and high level consent-related information add to the existing confusion about HIE and HIE-related concepts.

Fourth, these novel findings are important with regard to integrating population tailored approaches, such as user-centric design, into HIE consent-related interventions. This realization adds to current knowledge that technology alone is not sufficient even for a well-educated sample of PLWH. Hence, a standard means of HIE consent delivery may not cover the multifaceted needs of the PLWH population. Although most of the participants felt that the eConsent was useful and easy to use, almost half of the participants (45%) were unable to verbalize a single component of HIE. Hence, there appears to be a difference in perceived usefulness versus actual usefulness of the eConsent. The aim was to better facilitate the delivery and comprehension of HIE, but the results did not readily support that. Although the HIE eConsent was somewhat intuitive and interactive, some participants that had lower levels of comprehension were also not tech savvy, and as such, may potentially benefit from a hybrid consent approach that uses both a dedicated person and multimedia (Rothwell et al., 2014).

Of note, a comment made by one of the study participants (Appendix G) reported that the eConsent's interesting, colorful, and interactive design may potentially be distracting, and because of this, it may not be taken as seriously as a paper consent. Another participant considered the paper consent to be formal and thus should be taken more seriously than an eConsent. This participant also believed that the paper consent brought up perceptions of potential security breaches, such as hacking, due to the language of the consent that emphasized words such as "risk." Other participants preferred the eConsent's concise, "less is more" format. These findings support that more research is needed on effective, comprehensible strategies to address the comprehension needs of PLWH.

Last, the sociotechnical framework served as the overarching model for this study. This model highlighted the interrelated dependency of the eight domains. For example in Phase 1, internal organizational features (the clinics administration) influenced the people's (registration clerks) workflow challenges with the hardware/software and clinical content (Figure 16). Although not a part of this study, external rules and regulations mandate that written consent is obtained prior to electronic sharing of PHI. System measurement and monitoring was influenced by external rules and regulations as well as workflow, which was dependent on registration clerks having the time to discuss HIE consent with patients. In Phase 2, an eConsent facilitated interaction with clinic patients and has the potential to streamline the clinic workflow, supplement the current paper consent with an eConsent, and impact the number of patients that will consent to HIE. The sociotechnical model was critical to better appreciate the overall consent structure and patient needs regarding HIE at this clinic.

Dissertation Strengths

In phase 1, the researcher was able to observe firsthand the processes of patient registration. Because of this, workflow challenges were identified that would not have been able to have been assessed if not directly observed. Two significant artifacts of the observations were the flowchart and sequence model. The flowchart described the registration clerk's workflow and gave context to the process. The sequence model visually conveyed the points of interruptions in the flow of the registration process. Observational data contributed to identifying the challenges in facilitating HIE consent for the registration clerks. Multiple stakeholder perspectives were able to be obtained firsthand as opposed to relying on secondhand information.

As the key stakeholders and target for the Phase 2 pilot study, patients provided the richest data regarding what are perceived barriers to consenting. Also, patient navigators and clinicians contributed to the identification of barriers that patients may have been unable to articulate. Collection of real-life data can contribute to the knowledge and development of meaningful solutions in the context of HIE consent for PLWH. With regards to this study's sample, the PLWH racial and ethnic mix was representative of the overall PLWH population (Table 9) versus other studies that may have an overrepresentation of non-minorities. The data collection methods allowed the researcher to use triangulation (Denzin, 1970; Kimchi, Polivka, & Stevenson, 1991) as a means of corroborating the study findings.

The researcher valued the input of its HIV clinic participants, and as a result in phase 2, the researcher was able to design a user-centric eConsent that was specific to this clinic population. The study results convey how essential patients are in the research process. This is in alignment with Hunter's (2009) study that identified the lack of patient perspectives in research, which was in contrast to the ample research that is available about electronic sharing from the perspectives of healthcare providers and other stakeholders (Hunter, Whiddett, Norris, McDonald, & Waldon, 2009). Additionally, the three-tier layered approach that uses icons, text and simple language are novel in facilitating HIE consent to PLWH. Although other studies have developed multimedia interventions to better facilitate consent comprehension (Fink et al., 2010; Rothwell et al., 2014), this dissertation study differs in that both comprehension and user preference for an HIE eConsent were assessed in PLWH at a urban HIV clinic. To the researcher's knowledge, this is the first study to utilize multiple methods and data sources to design an informatics-based HIE eConsent for PLWH. No publications were identified that used a sample of PLWH to design an eConsent to better facilitate HIE consent at an HIV clinic.

Limitations of Phase 1

In Phase 1, the sociotechnical analysis, there were limitations related to sample size, setting, and the re-use of an existing data set. In all methods, participants represented convenience samples. In addition, with the exception of the analysis of existing survey data, the sample sizes were relatively small for each method. All data except for the survey data were collected in a single HIV clinic, which limits the generalizability of the study results. The analysis of willingness to share PHI used existing data, and therefore the research questions, were limited to questions that could be answered with the existing survey data.

Limitations of Phase 2

In Phase 2, the user-centered design and eConsent pilot testing both used convenience sampling. Although convenience sampling is inexpensive and less time-consuming, it may have contributed to potential participant selection bias. Moreover, both aspects included small samples, which may not be representative of all PLWH. The number of analytical techniques that could have been performed on the Likert-scale data to assess perceived ease of use and usefulness was limited due to the small sample size. The post-test only design did not allow comparison of change in comprehension or differences in comprehension between the two consent formats. Next, since the researchers could not locate a validated tool to measure HIE consent comprehension, qualitative open-ended questions were used to assess HIE comprehension. Finally, self-reported data obtained from the semi-structured interviews, questionnaires, and surveys were all subject to recall and response bias.

Implications

The study findings have implications for research, practice and policy.

Implications for research

This dissertation study was limited to one HIV clinic to assess preference and perceived ease and usefulness of eConsent prototype for HIE as well as HIE comprehension after both consent types. There are opportunities to build upon this research to better elucidate the facilitation of HIE consent among PLWH. First, generalizability can be improved for other PLWH populations by increasing the sample size. This can be accomplished by a multi-site study and allow for a more representative sample. Second, an experimental pre- and post-test design using a stratified sample based on gender, age, race, income and geographic location would strengthen the study design by examining differences in comprehension between eConsent and paper. Stratification ensures that there is adequate representation in the participant sample (Burns & Grove, 2009), as this study had an overrepresentation of males and African Americans. Third, incorporating validated measures to assess comprehension will increase the validity of the study findings. To date, there are no validated instruments that measure comprehension of HIE prior to or after obtaining affirmative consent. This is problematic as PLWH come from diverse backgrounds racially, ethnically, economically and socially, and there is a critical need to deliver HIE consent-related information in a comprehensible way. This lends to possible research for the development of such a validated instrument.

Implications for practice

The literature has suggested that hybrid formats of consent are potentially beneficial, and in this study, PLWH used an iPad but were not provided with discussion or guidance about HIE. Patient navigators were noted as trustworthy individuals, and the literature has suggested that the usage of multimedia in facilitating comprehension could be advantageous. Thus, exploration on the potential benefits of using a hybrid consent structure that utilizes patient navigators and an eConsent is warranted. Jaded and Enkin (2008) argued that informed consent strategies should extend beyond paper legalese and incorporate various methods, such as pictures, graphs, discussion boards and informational videos (Jadad & Enkin, 2008). They contended that one model of delivering consent is not suitable to result in all individuals being fully informed (Jadad & Enkin, 2008).

By extending this dissertation research and incorporating a hybrid, multimedia approach, best practices for the delivery of HIE consent-related information can enable PLWH to better understand what is being signed. Looking forward and expanding on the work of Wilbanks (Sage Bionetworks, 2015b), an adapted three-tiered approach to target PLWH could include: (1) a dedicated person, (2) multimedia consent, and (3) a paper consent. This approach could potentially be strengthened by incorporating training on how HIE consent should be delivered by a dedicated person, so that all encountered individuals receive a uniform discussion of the important components of HIE. This would be similar to a study research protocol and the training that the research staff undertake so that they can deliver study consent procedures in a uniform, unbiased fashion.

Implications for policy

Clinics and provider organizations should assess workflow issues that may potentially impede facilitation of HIE comprehension. Consent forms and other HIE consent-related documents should be created at a comprehensible reading level, using the recommendations from top scholars in the literature, which would include appropriate reading levels and minimal legalese. Facilities may benefit from examining their own policies on how their HIE consents are being presented to their own patient population and compare their documents to similar organizations or clinics. This may improve the delivery of HIE consent through process changes. At the organizational level, policy regarding HIE consent comprehension should be assessed and uniformly applied to the PLWH population. In this dissertation study, patients considered the eConsent to be easy to use and useful but did not always comprehend the HIE content. A dedicated person can review and have a brief comprehension discussion with the patient to improve their informed decision making.

Conclusion

As a vulnerable population, PLWH may experience an array of perceptions (e.g., fear, distrust, stigma) that influence their decision to electronically share their PHI; yet to the researcher's knowledge, user-centric approaches to address HIE consent for PLWH that utilize a three-tiered approach (icons, simple text and a full consent document) have not been sufficiently studied. This study is timely as the utilization of technology in health care, including HIE, continues to flourish, and PLWH of all backgrounds can benefit from innovative user-centric strategies to improve the delivery of HIE consent materials. A step-wise approach from Phase 1 to Phase 2 illustrated the value of using multiple methodologies and frameworks to understand the barriers to HIE consent and to design and pilot test an intervention for addressing one barrier. This study supports further exploration on how to best deliver and facilitate HIE consent-related information to PLWH in order to improve their decision making about electronically sharing PHI.

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Appendix A: Stakeholder Interviews

Initial categories and related quotes from **Registration Clerks**

Category		Select Quotes
Time	Facilitator	"More time to discuss it and if the patient understands exactly what they're signing, they're more likely to agree to it. It's just if we have the time to sit down and actually explain it to them, yes. They'll agree to it."
	Barrier	"Like a lot of patients come at one time, so it's hard to get every information from them. So sometimes when we do catch it, if we do miss it and we catch it at the end of the visit, then that's good too." "Mainly time constraints, due to the fact that we have a large volume of patients coming in at one time, sometimes. Some patients get overlooked as far as offering the exchange forms. But most of the times we do try to play catch-up to it, like backlogging it and make sure that it's done, maybe after the visit. We ask not before, but after the visit. We ask them if they could sign it." "Well, barriers in the clinic, yes, it's time. Because in order for them to agree 100% to sign, you have to explain to them what it is. Ok and after they understand what it is, right away they sign it. So, it's just time."
Distrust/Fear	Barrier	"No, it's just about who's looking at it. That's all mainly, like who's going to know?" "Even though they understand, I just feel like that barrier, they build it themselves just because they're scared and they don't know who to trust. Because we've also…well this is just earlier in fact. But like if they see somebody they know, like on the floor, they don't want that person to know. And we've had that happen, so. It's all about, I say it's trust and they're scared at the same time." "Like I say before, because they are not confident with the fact that we're going to keep that information private and confidential."
Dedicated person	Facilitator	"Dedicate a person to get this, you know get the patients to agree. And have time, enough time with the patient to explain." "I was doing this in the beginning, when they just started here. Believe me; I got maybe 98% of the patients to sign the consent, because I was sitting with the patients myself. And I was explaining to them what was going on and why. And how they're going to benefit with it, ok. So that's the answer."
HIE Consent form exposure	Barrier	"Because I was told briefly about the form, but I wasn't…it was very brief, like I'm more aware of the HIPAA form than this one. This form is not given everywhere of course, with every patient. I'm aware of HIPAA because I received them myself as a patient. But with the HIV form, you know it's strictly to just HIV patients. So, for someone coming into this field, into the medical field and treating HIV, I think that it's better to make them more comfortable and more knowledgeable about the paper, the consent form."

Initial categories and related quotes from **Patient navigators**

Category		Select Quotes
Knowledge of clinic's consent process	Barrier	"I'm not involved in that process. I don't know. I mean as far as sharing information, it's like the best idea because it saves us a lot of time. And finding out where the patient has been, sometimes they can be in a hospital or something and we don't know." "I don't know if here they can view that they're going to another facility. I really don't know. But it would be a great thing because this patient has said multiple times that she's been in that hospital, and we have no idea until she tells us."
Patient education of HIE	Facilitator	"Just by explaining to them what it is and just basically probably telling them like, listen, if you get sick somewhere else and you go to another hospital, is that better care, not to get you worse and give you some other medication that you're not taking already to or whatever the case may be, that at least have a list of what you're on and continue." "I think education is the key to everything. You know you explain to people why you've got to do something or why we feel that it's good for you to do X, Y and Z, if you don't explain it to them in terms of like how does that benefit me? Then they're not going to…you know what I mean?" "You know talking to them about it, educating them so that when they go to the clinic, they have more information and they know what it is."
Patient Trust	Facilitator	"They call us for everything. Oh, my Medicaid is disconnecting. Well, you have a social worker for that. It's funny because we educate them about this. That's the role of the navigator. You tell them where to go…. But sometimes it is easier to just do the service for them and get it done. And then they kind of get used to that too. That's the bad part….Sometimes it's difficult to say no. Sometimes it's difficult to draw a line. But you know you have to. You have to draw the line. They want you to do everything for them." "They'll call you for everything. I mean they'll call me for like my iPad is not working. I've gotten calls on the weekends, like my iPad is not working because they know I'm like a technical person. You get those types of calls too. It's not only like medical stuff. My phone doesn't work. My iPad doesn't work. I don't know; the switch doesn't turn on. You get those types of calls." "Even the doctors when the patients act up in their rooms. They call us."

		"I mean we have to take up so many different kinds of roles. Sometimes we have to be the counselor, even though we don't want to. I have found myself in situations where I have to listen to the daughter and mother talk about issues they're going through. And I'm not a counselor, like I'm not trained for that. And I have to find a way to kind of leave there without having them feel worse or feel like they don't have that kind of support. Like an instance was where I had to try and get the daughter to kind of agree to go and see a therapist of her own, because the mother was seeing a therapist…..They're not where they should be like you know, mental health-wise. And then I feel very uncomfortable having to assume that role because obviously I'm not a counselor. I didn't study for that; I didn't go to school for that."
Integration into clinic patients lives	Facilitator	"I have a patient, like right now she's in ICU and they're going to disconnect her machine. Her son called me crying because he's seen me for a year and a half. So it's like you kind of become part of the family. So he was like oh, I want you here. So you kind of have to deal with that part." "I don't get too really attached to the patient. You know I'm kind of not cold but like I separate it really well. "Or sometimes, for example, had a patient who passed away two years ago and they called the social worker to deal with the family. The social worker calls me because I know the family. You know so it's me, the social worker and this dead body there for over an hour and a half. And I'm sitting in this room alone…dead body, you know? And people don't see that part. And that's the part that always gets to me."

Stakeholder Interviews

Initial categories and related quotes from **Clinicians**

Category		Select Quotes
Registration clerk demands	Barrier	“They [registration clerks] actually have to work two separate computer programs. They have to answer all of these phone calls. They have to get everybody’s labs released. They have to submit all of the billing… they probably have ten or twelve things that they do per patient, while they’re answering the phones and triaging, problems.” “My guess is that our front desk staff [registration clerks] gets overwhelmed and busy, and is often running behind. And it would be my guess that they probably very often don’t even mention it to patients.” “Because you know of the multiple tasks that the [registration clerks] have to do in order to process the patient in and out. I think that is a low priority, unfortunately. And it would be really nice if it could just be streamlined into the check-in somehow.”
Dedicated person to discuss HIE	Facilitator	“You know I think you can get at those issues and explain them and get people to consent with a dedicated person out there, kind of explaining it and also highlighting it because again they get this big package of paperwork with all of this stuff happening.” “You know we have some premed student volunteers. We have, you know there are lots of people who could do it, even on a voluntary kind of relationship basis.” “I think the highest priority is to actually find someone with the time to take the patients through the process.”
Clinician support	Facilitator	“Well, I think you know if they [the patient] have a good relationship with the provider, which I think most of our patients do. You know get the providers involved.” “I’m really not; you know I’m not informed about the process. So, you know I don’t know which of my patients have consented or which haven’t. You know but if I was given that information, I might encourage some who have refused to reconsider it.”
Clinician time constraints	Barrier	“The other option, you know and it’s crossed my mind, would be to have the clinicians doing it in the office. But, it would take up time that you’re trying to use for other things with the patients.” “And again, this goes back to the time issue, if you’re really going to be available to answer people’s questions, now you’re talking about a time-consuming process.” “I think the highest priority probably is to actually find someone with the time to take the patients through the process. “

Stakeholder Interviews

Initial categories and related quotes from **Patients**

Category		Select Quotes
Limited knowledge of HIE/ Inability to distinguish with HIPAA	Barrier	"For me, I have to sign HIPAA forms for different information to get released. If it does not, if I don't sign that HIPAA form, like say for instance, I'm going to mental health. I have to sign a release form for them to get the information. If I'm going to Bronx-Lebanon I still have to sign that HIPAA form to state that it's ok for them to get that information. Majority of the time they can't get it, so the HIPAA form says you can or I designate that you can get it." "Is it a HIPAA form?" "What is this form for? You signed this for what?" "Just like the HIPAA almost, no?"
Time	Barrier	"When you're meeting your physician, I mean because you're going over so many other stuff and I'm not saying that they're not up-to-date, sometimes they sort of defer paperwork to the registration people. "You know I'd like it if my doctor then great, fifteen minutes, boom. You know there's more things that just going over my labs. You know and we have those sit-downs for a minute but it's not as in-depth or as you mentioned that conversation that someone who specifically is doing this, like a patient navigator." "And then the flipside of that is that the people that are doing registration, they have so much else going on that they may not be able to give you the individualized attention that you need, to help you with your questions." "And also registration, they're bombarded, you know at times, phone calls, people want things. So it's busy up there too."
Lack of trust	Barrier	"I need to be able to regulate or control who's going to get what type of information. That's important to me." "I think that I need to be in control about who I want to share my HIV status with. And maybe some doctors, they really just don't need. I mean you know I don't have an issue with it. If you don't need to know it, then I don't want to share that information." "You know this is going to create all types of things, fraud, identity theft, all of these things are going to come into play when this becomes more widespread."
Stigma	Barrier	"..other agencies that would be able to tap into that information and making judgments or prejudgments or not even you know just because they have access to your medical record, to make judgments with budgets and who knows what else." "She [an eye doctor] refused to come back and deal with me. And so like that's what I'm saying about the whole…there's

			still discrimination. There's still stigma. And I want to be able to put safeguards into place, in which…because it is a good thing. I mean I like the whole granting of access of information."
Dedicated person		Facilitator	"So if there would be one other person who would be a little bit more designated… Right, to handle this kind of stuff, then I would feel more comfortable because doctors are usually sometimes; they're not always up-to-date on paperwork stuff." "I concur with them as far as someone specifically…that'd be someone's specific job responsibility as it relates to this health consent." "And you know if you have an issue with someone at the front desk, maybe you may not want to go to them and say, look, you know so a designated person would be good, but also security." "…you would probably want to sit with somebody who can better go over those forms with you."

Appendix B: Icon Interview Participant Selections

Question #1 Which picture best represents a person thinking about what is HIE?

P1: “Yeah the person thinking about something.”

P2: “The question marks insinuate that he’s [the icon] is in thought.”

P3: “The color stands out” – somebody’s thinking about it.

P4: “The person bc he’s a human Looks like he’s thinking about something.”

P5: * Selected the human pondering and surrounded by question marks.

Question #2 Which picture best represents a person thinking about what information can be accessed about me”

P1: “This looks like computers to me - so it looks like they’re communicating.”

P2: “If you’re getting them [information] from different place, this would represent what entity you’re getting it from.”

P3: “The iPad”

P4: “Bc its downloading and uploading.”

P5: * Selected the icon of two monitors uploading and downloading to a cloud.

Question #3 Which picture best represents a person thinking about who can access my information?

P1: Selected the person looking at the computer

P2: “Assume that the person at the computer has an access code and the picture reflects a medical professional.”

P3: Selected the person reading at the laptop

P4: “Being from medical, it would have to be the guy with the stethoscope. Definitely looks medical.”

P5: * Selected the medical icon with the stethoscope and headlamp

Question #4 Which picture best represents how is my information protected?

P1: “There’s a lock on the screen”

P2: “Its on the terminal its locked and secure and not easily accessed.” – identified firewalls and server system [knowledge of technology].

P3: “Represents this is how my information is being protected.”

P4: “The lock on the screen. Like a key like a password or something to access. It looks like a screen and its locked and you need a password to get in.”

P5: * Selected the computer monitor with padlock on screen

Question #5 Which picture best represents what are my options for consent?

P1: Selected pen in writing hand

P2: Selected checkboxes

P3: “The checkmarks just make sense.”

P4: “You get an option – check for yes or ex for no.”

P5: * selected the paper and pen

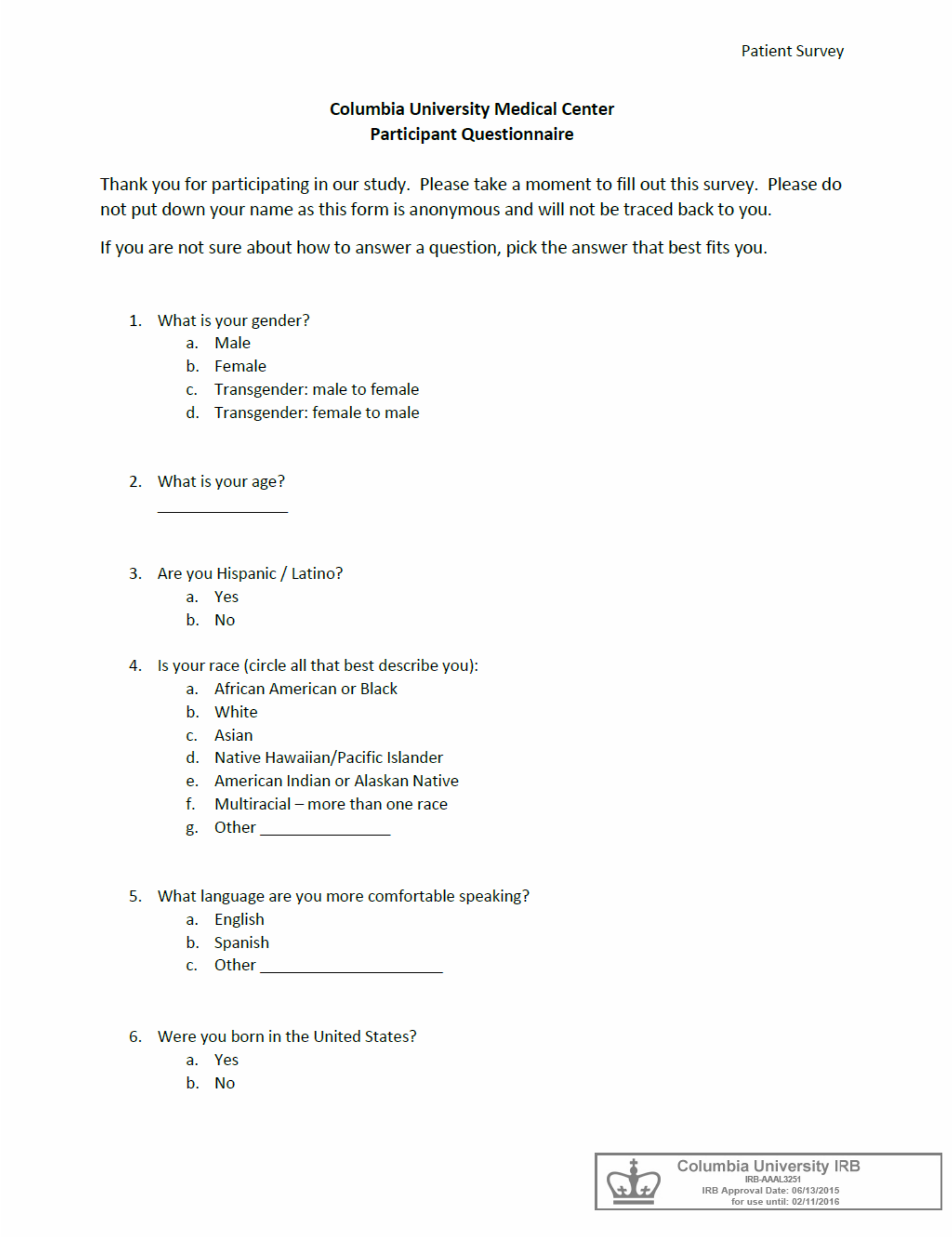
Additional Participant Comments:

P1: “I think when you present information to people that it should be as clear and understandable as possible. Something they can relate to. No big words and all that kind of that stuff. Give them a fair understanding of what they need to know.”
Researcher Note: *Concerned if their responses were similar to other people.. [Pressure to be “correct?”]*

P4: “I assume that [HIE] it is supposed to make your information more accessible.” –
Researcher Note: *Brought up example of going to a hospital in the Bronx and that borough’s hospital not being able to access his NYP medical records because they could only access Bronx borough records. He hopes that HIE is accessible throughout all boroughs*.

Note:
P5: Provider walked in and said participant’s name. Voice recording not used. Researcher wrote participant responses.

Appendix C: Demographic Questionnaire



Patient Survey

Columbia University Medical Center
Participant Questionnaire

Thank you for participating in our study. Please take a moment to fill out this survey. Please do not put down your name as this form is anonymous and will not be traced back to you.

If you are not sure about how to answer a question, pick the answer that best fits you.

1. What is your gender?
   a. Male
   b. Female
   c. Transgender: male to female
   d. Transgender: female to male

2. What is your age?
   ____

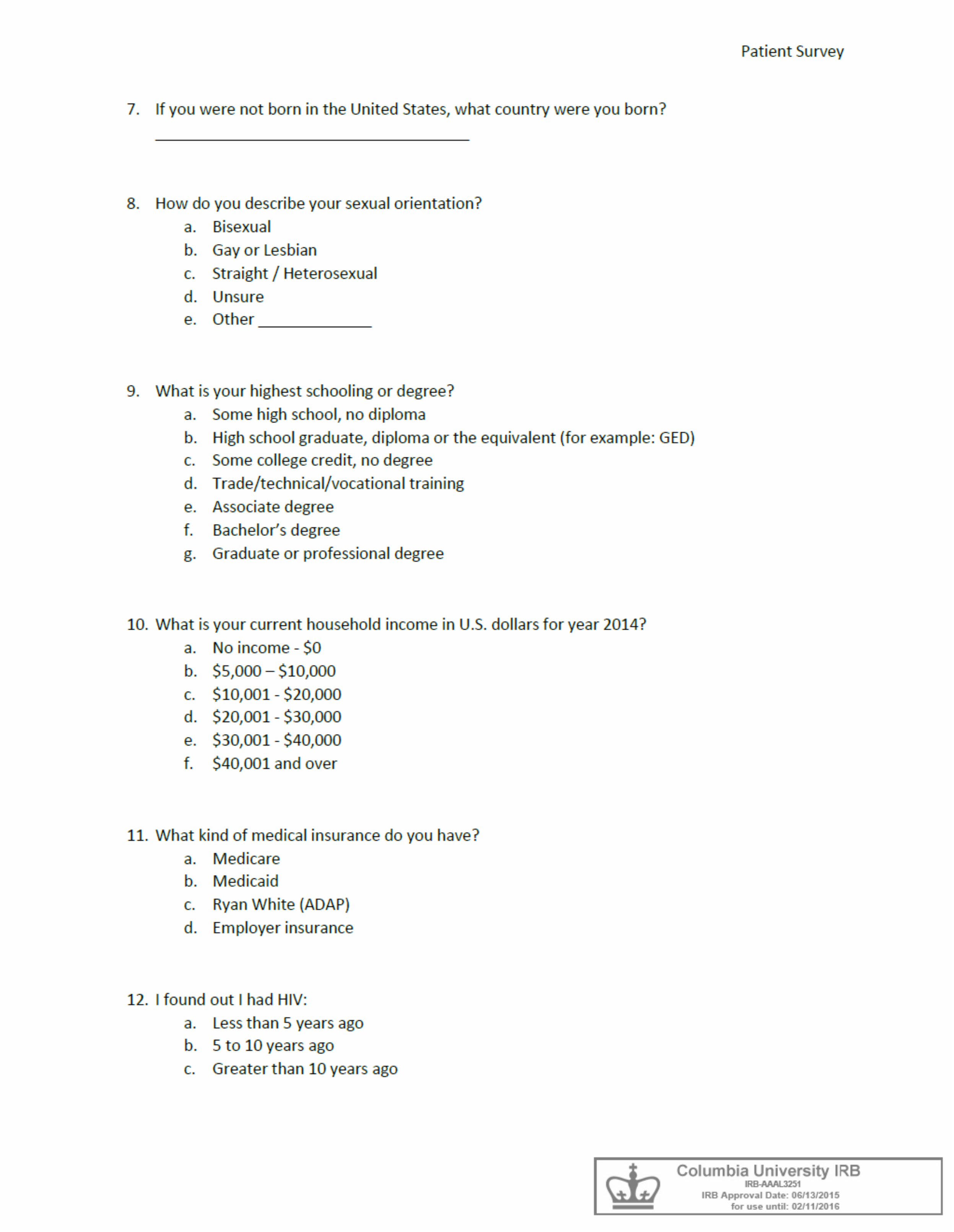
3. Are you Hispanic / Latino?
   a. Yes
   b. No

4. Is your race (circle all that best describe you):
   a. African American or Black
   b. White
   c. Asian
   d. Native Hawaiian/Pacific Islander
   e. American Indian or Alaskan Native
   f. Multiracial – more than one race
   g. Other _______________

5. What language are you more comfortable speaking?
   a. English
   b. Spanish
   c. Other _____________________

6. Were you born in the United States?
   a. Yes
   b. No

Columbia University IRB
IRB-AAAL3251
IRB Approval Date: 06/13/2015
for use until: 02/11/2016



7. If you were not born in the United States, what country were you born?

   ____

8. How do you describe your sexual orientation?
   a. Bisexual
   b. Gay or Lesbian
   c. Straight / Heterosexual
   d. Unsure
   e. Other ___________

9. What is your highest schooling or degree?
   a. Some high school, no diploma
   b. High school graduate, diploma or the equivalent (for example: GED)
   c. Some college credit, no degree
   d. Trade/technical/vocational training
   e. Associate degree
   f. Bachelor's degree
   g. Graduate or professional degree

10. What is your current household income in U.S. dollars for year 2014?
    a. No income - $0
    b. $5,000 – $10,000
    c. $10,001 - $20,000
    d. $20,001 - $30,000
    e. $30,001 - $40,000
    f. $40,001 and over

11. What kind of medical insurance do you have?
    a. Medicare
    b. Medicaid
    c. Ryan White (ADAP)
    d. Employer insurance

12. I found out I had HIV:
    a. Less than 5 years ago
    b. 5 to 10 years ago
    c. Greater than 10 years ago

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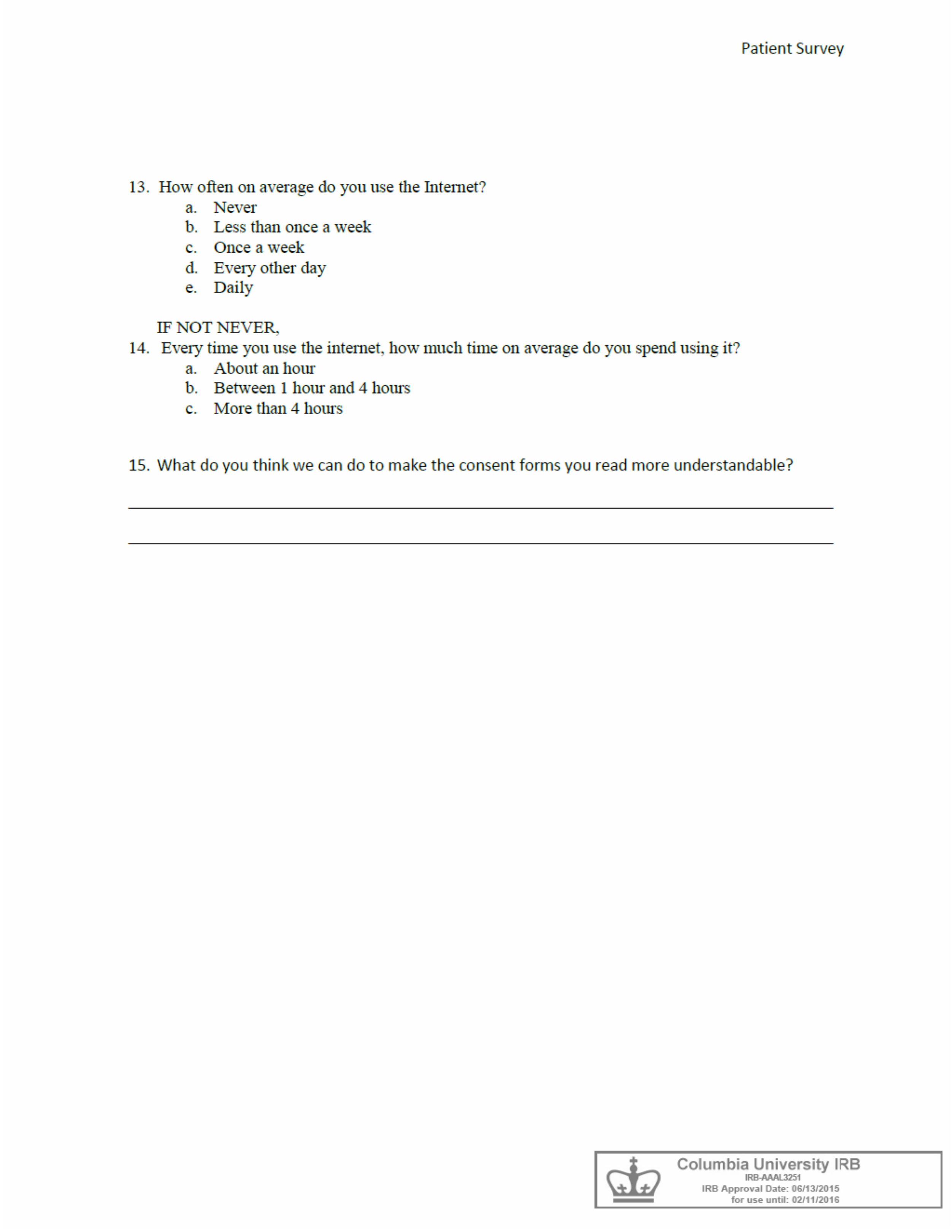


13. How often on average do you use the Internet?
    a. Never
    b. Less than once a week
    c. Once a week
    d. Every other day
    e. Daily

IF NOT NEVER,

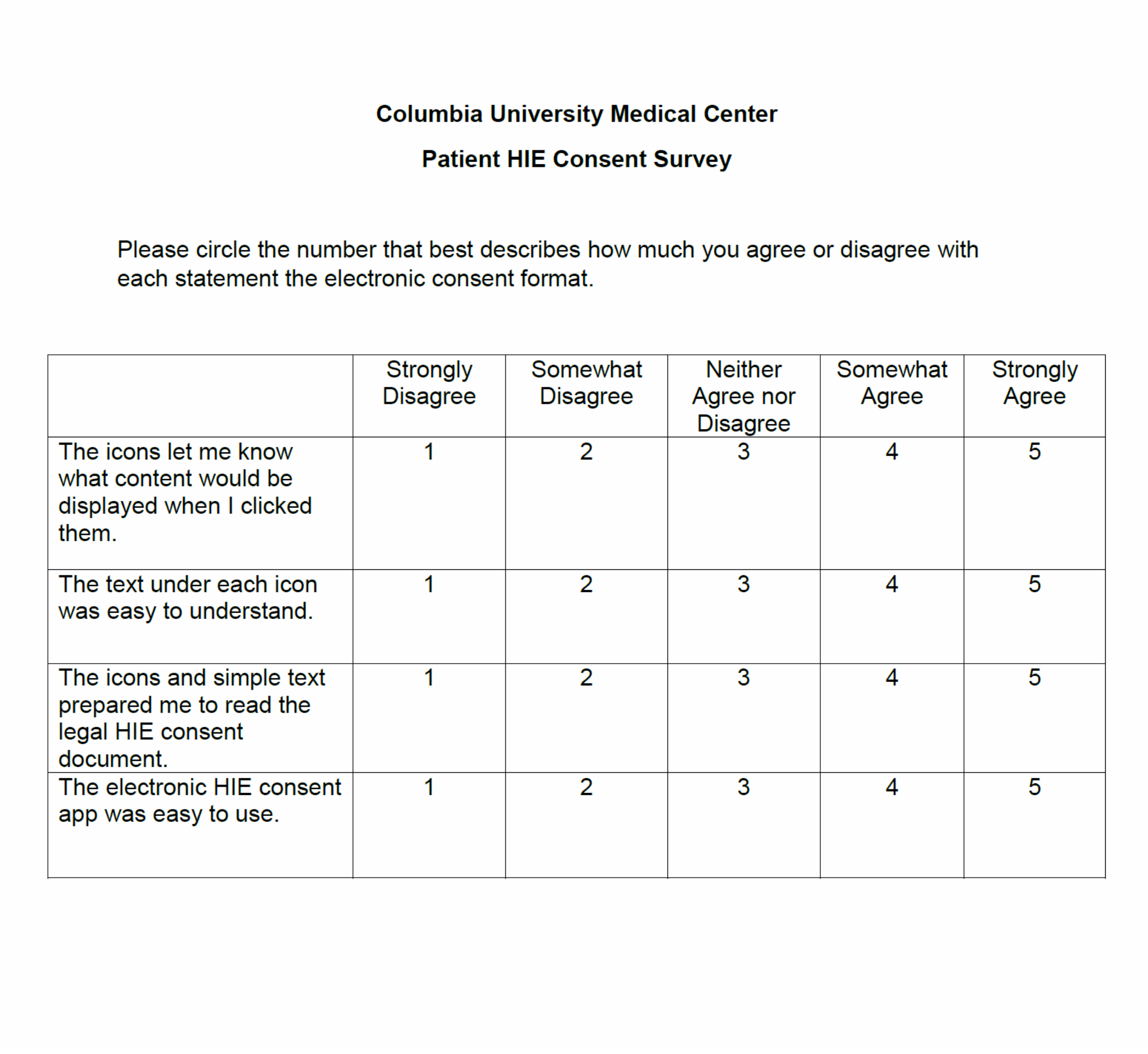
14. Every time you use the internet, how much time on average do you spend using it?
    a. About an hour
    b. Between 1 hour and 4 hours
    c. More than 4 hours

15. What do you think we can do to make the consent forms you read more understandable?

____

____

Appendix D: Patient HIE eConsent Survey



Columbia University Medical Center

Patient HIE Consent Survey

Please circle the number that best describes how much you agree or disagree with each statement the electronic consent format.

	Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
The icons let me know what content would be displayed when I clicked them.	1	2	3	4	5
The text under each icon was easy to understand.	1	2	3	4	5
The icons and simple text prepared me to read the legal HIE consent document.	1	2	3	4	5
The electronic HIE consent app was easy to use.	1	2	3	4	5

Appendix E: Patient HIE Consent Comprehension Semi-structured Interview Guide

Columbia University Medical Center

The electronic collection, transfer and accessibility of protected health information is known as health information exchange (HIE). In New York State, a patient has to sign a written consent that affirms their decision to electronically and securely share their medical information with other clinicians that care for them. Residents of NYS can "opt-in" or "opt-out" to this statewide HIE.

We are talking to patients associated with the New York-Presbyterian HIV clinic. After completing both consent documents, the paper and electronic versions, we would like to know your perceptions about which version was more understandable. Thank you for agreeing to share your comments with us.

1. In your own words, tell me about HIE.
2. Tell me your thoughts about HIE after using the paper version.
3. Tell me your thoughts about HIE after using the electronic version.
4. Which document format do you think clearly explains HIE? Why?

Appendix F: Participant Responses and Scores to HIE Comprehension Interviews

In your own words tell me what is HIE?

P = Participant

Scoring

[0]Low comprehension = unable to report any essential component of HIE
[1]Moderate comprehension = ability to report one essential component of HIE
[2]High comprehension = ability to report one or more essential component of HIE

P1: "It's an exchange of health providers of all places you've been treated so it's your entire medical history where ever you are." Score: 2

P2: "It's about my status my sickness, my medications and my doctors." Score: 0

P3: "I would be consenting to RHIO which basically information would be given to clinics and doctors and only healthcare providers would be able to see the information." Score: 1

P4: "Easier way to access your information, especially if you're not in a way to coherently speak for yourself." Score: 1

P5: "Its having accessibility to my health records." Score: 0

P6: "It provides electronic information to the clinic you go to. To the doctors that takes care of you. Can understand more of what they're dealing with." Score: 1

P7: "It's a program where your medical doctors have access to your medical records whether it's at the clinic or outside of the hospital and lists the health conditions that I have and what treatments I have gotten. You must sign a consent form to have the doctors' access my information." Score: 2

P8: "A system for putting together and providing access to health records of patients." Score: 1

P9: "Essentially allows healthcare providers to access your information at what hospital, clinic or doctor your may be working with. So it sorta connects everybody." Score: 2

P10: "From what I understand it's supposed to be the Healthix.. I believe it so the doctors that are giving you medical care can keep a connection and directly correspond with each other to know what to do and know your care to treat you better." Score: 2

P11: "HIE is when you have privacy. The way I understood it.. when you have privacy in the facility where you receive the medical care an you decide you want medical care elsewhere you would get a consent." Score: 0

P12: "Health information exchange, it provides electronic access to treatment providers. This can be anywhere that the HIE exists." Score: 2

P13: "Its about your health, your HIV status, your TCells and uh viral and TCells. It tells you about your health. What meds to take. Helps you stay healthy with your HIV status." Score: 0

P14: “It’s a way for other medical institutions to access my health information electronically without having to make all of these crazy calls or faxes. If I ended up at Beakman downtown they would be able to access.” Score: 2

P15: “To me it’s about my blood tests, what you provide to the hospital. Its lets you know about yourself.” Score: 0

P16: “It tells you what are the best things to do and take care of your health because it’s very important to know your status.” Score: 0

P17: “HIE it’s not HIV? HIE its more less the… What’s HIE?” Score: 0

P18: “Health information is to tell you how the hospital works with a patient. What happened, if getting satisfactory work done.” Score: 0

P19: “It’s about the research with the HIV thing.” Score: 0

P20: “It’s about the whole process of how if I were injured another hospital my doctors can always check back on the information from the other hospital. They can always access what was done what was administered to me if I was outside of my healthcare circle.” Score: 2

Appendix G: Participant response to HIE consent form preference

(PAPER OR eCONSENT)

P1: "I want the information out there so that there's a place to start. Because a person can die if you're alone. The iPad was easier to read. I would want it blown up a little more [the words] but it was fine. I grew up reading 3 papers a day. It's nice to have the electronic. Growing up we never had computers or phones….still prefer the paper form. [participant preferred the paper consent]"

P2: "Helps me understand electronic things more than the paper. I need glasses and the electronic is easier to use."

P3: "Being that technology is more advanced I prefer the electronic [format]."

P4: "It [eConsent] was less intimidating and more to the point. Less is more and this was more. This delivers more in less time and is not as intimidating [as a paper consent]. Since we live in an age of technology, people are just more familiar with it and even people that aren't are going to find it [eConsent] easier."

P5: "I like the iPad. It's more concise. It's straight to the point. The paper version is stretched out. It's longer… it's a deterrent to a lot of people too. Especially if their reading capability is not… well attention span is… so that can be a real hindrance. A lot of people are gonna gravitate towards that [eConsent] because if you're not a reader, you'll be very despondent."

P6: "The paper version is kind of long… too many words.. I read everything but some people will not be reading it. It was so simple. It tells you what it is. It gives you the important things first and I understood it perfectly."

P7: "Electronic is pretty simple and easy to use. Quick access. The letters are in a format that are easy to read. I think that anything that is written can be kept as a copy and be read over again and the iPad can have electronic problems and crash. It's nice to have a hardcopy, but also have a version on the iPad. It's more visual and graphical."

P8: "It [paper version] was a lot of information to remember and understand, the type was small and there was a lot of information so it took a lot of time to read it all. I'm not sure that I read every word so it's sorta cumbersome. Certainly more entertaining [the eConsent] if just for the colors used. It's hard to believe that it had all that information on it. It seemed so accessible. The electronic was easier and more inviting. More easy to read."

P9: "Honestly, I would never read this much information. Um, if I see it I would just sign it – yeah that's too many words for me right there. I generally do not read those types of things. I think the electronic version is simple to use. I would read that because they're more simple, concise paragraphs. I guess more interactive and I'm used to that. All of the information is essentially given. I use the computer. I have an iPad and all that so um to me it's very convenient and it's less paper to deal with. I prefer electronic because I think that's where most things in life are going in general."

P10: “It’s long and drawn out [paper consent]. The electronic version is a much easier way and understandable way to know what’s going on. Simpler is always better.”

P11: “The paper version was understandable, clear, precise and informative.” “It was very easy to use. It made a lot of sense.” “I prefer the electronic so I prefer using the computers.”
Researcher Note: *Participant could not define HIE and reported understanding both consent formats.*

P12: “The electronic version was easier to use. The paper version…. I think that the electronic version provides for more visual cues. Um, and it seems more concise as well.”

P13: “It [paper consent] was very understanding. It [eConsent] is also understanding. I like it. But, I’d pick the paper because I could take my time reading it.”

P14: “I thought more about hacking from reading the paper consent, because growing up reading documents and paper I learned to read between the lines. Whereas the computer on the technology seemed so fun and it’s almost like playing a game that you don’t think of it as a legal document. So paper makes me think, ‘what am I signing?’ and I’m not signing anything on the tablet but if I sign a piece of paper I think I may pay more attention to the paper.”
Researcher Note: *Technology or the eConsent could be distracting – may not be taken as seriously.*
Additional Participant Comment: “The electronic version would make it easier for people I’d want to have access to have access. But it would also make it easier for the people that I do not want to have access to have access if the HIE was hacked.”
Researcher Note: *Security issues are still a barrier.*

P15: “It’s very good [paper consent]. It tells everything about the consent very well. In today’s world, the paper stuff is not being used. It’s all about the computer. “[Participant preferred] The paper I can keep it and see it.”
Researcher Note: *Could not define HIE, likes the eConsent format but still prefers paper consent because he can keep it and see it.*

P16: “It [paper consent] was more confusing but I got to know where I stand. “It [eConsent] helped me out in a way to understand what was going on. For me, the words I didn’t really understand how to read it, but I felt like I needed help and some words I didn’t know, you know? Even though I was doing it on a computer, I would really do it on a paper. The paper helped me sound the words out.” In some ways I understand and some ways I didn’t [the eConsent].”
Researcher Note: *Knew the paper was confusing but still felt that the paper was good because the participant would get better care. So without understanding, the participant felt that signing the paper consent was the right thing to do.*

P17: “I was surprised because of the difference [paper consent]. I like the electronic version because sometimes they ask you and you don’t have to go through those stages. It was simpler.”

P18: “I think the paper version explains it better because it gives you the words instead of just the icon. You have a better understanding with the words. The electronic is good. I guess I would do better with the paper because I’m used to it. The electronic is easy but I’m used to paper even though it is more tedious.”

P19: "I think it was alright [paper consent]. I didn't really understand it but it was alright. The electronic version was much better. It was much better to press the buttons."
Researcher Note: *Did not comprehend the electronic version but preferred it. Perhaps because its interactive?*

P20: "The online version is much shorter. It's straight to the point and there not so much paperwork. It was more descriptive and the online version was a cut down version that was more straight to the point. It was a summary. Depending on what state of mind that I'm in, I think that the electronic version is just much more easier, accessible and comfortable to deal with than having to do the long version. Who wants to read 3 paragraphs? Instead of read her tap there – much easier."

Overall Researcher Notes:

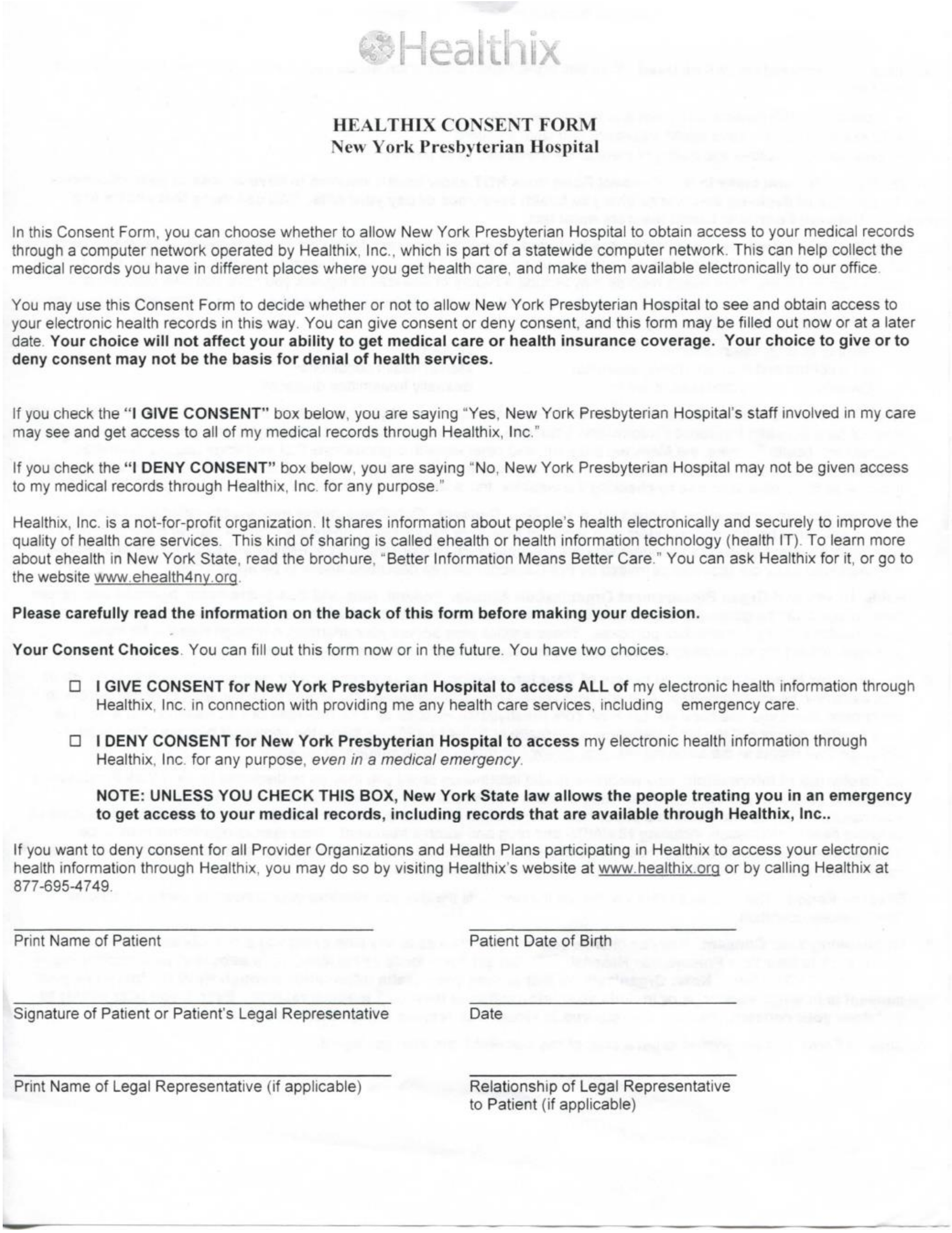
Even for those participants with higher reported education (ex: a participant discussed how they were involved with 'organ procurement'), comprehension was still low. Persons who were able to read words with greater than three syllables (i.e. electronically, environment, etc.) were unable to comprehend the content.

Although the eConsent was designed with low syllable counts, simple wording, less than ten words per sentence, and small paragraphs, participant comprehension was still limited. Exposure to this type of content is limited to healthcare environments and comprehension varied despite of education level.

There was an inherent feeling of positivity among some participants that couldn't understand the consent content. They believed that it was something good that would benefit their overall health. This perpetuates the 'culture of uninformed consent' where patients just routinely sign forms that are given to them at the point of care.

Because healthcare legal departments write consent forms, clinicians should be directly involved in HIE consent discussions with patients because they understand the consent literature.

Appendix H: HIE Paper Clinic Consent



Healthix

HEALTHIX CONSENT FORM
New York Presbyterian Hospital

In this Consent Form, you can choose whether to allow New York Presbyterian Hospital to obtain access to your medical records through a computer network operated by Healthix, Inc., which is part of a statewide computer network. This can help collect the medical records you have in different places where you get health care, and make them available electronically to our office.

You may use this Consent Form to decide whether or not to allow New York Presbyterian Hospital to see and obtain access to your electronic health records in this way. You can give consent or deny consent, and this form may be filled out now or at a later date. **Your choice will not affect your ability to get medical care or health insurance coverage. Your choice to give or to deny consent may not be the basis for denial of health services.**

If you check the **"I GIVE CONSENT"** box below, you are saying "Yes, New York Presbyterian Hospital's staff involved in my care may see and get access to all of my medical records through Healthix, Inc."

If you check the **"I DENY CONSENT"** box below, you are saying "No, New York Presbyterian Hospital may not be given access to my medical records through Healthix, Inc. for any purpose."

Healthix, Inc. is a not-for-profit organization. It shares information about people's health electronically and securely to improve the quality of health care services. This kind of sharing is called ehealth or health information technology (health IT). To learn more about ehealth in New York State, read the brochure, "Better Information Means Better Care." You can ask Healthix for it, or go to the website www.ehealth4ny.org.

Please carefully read the information on the back of this form before making your decision.

Your Consent Choices. You can fill out this form now or in the future. You have two choices.

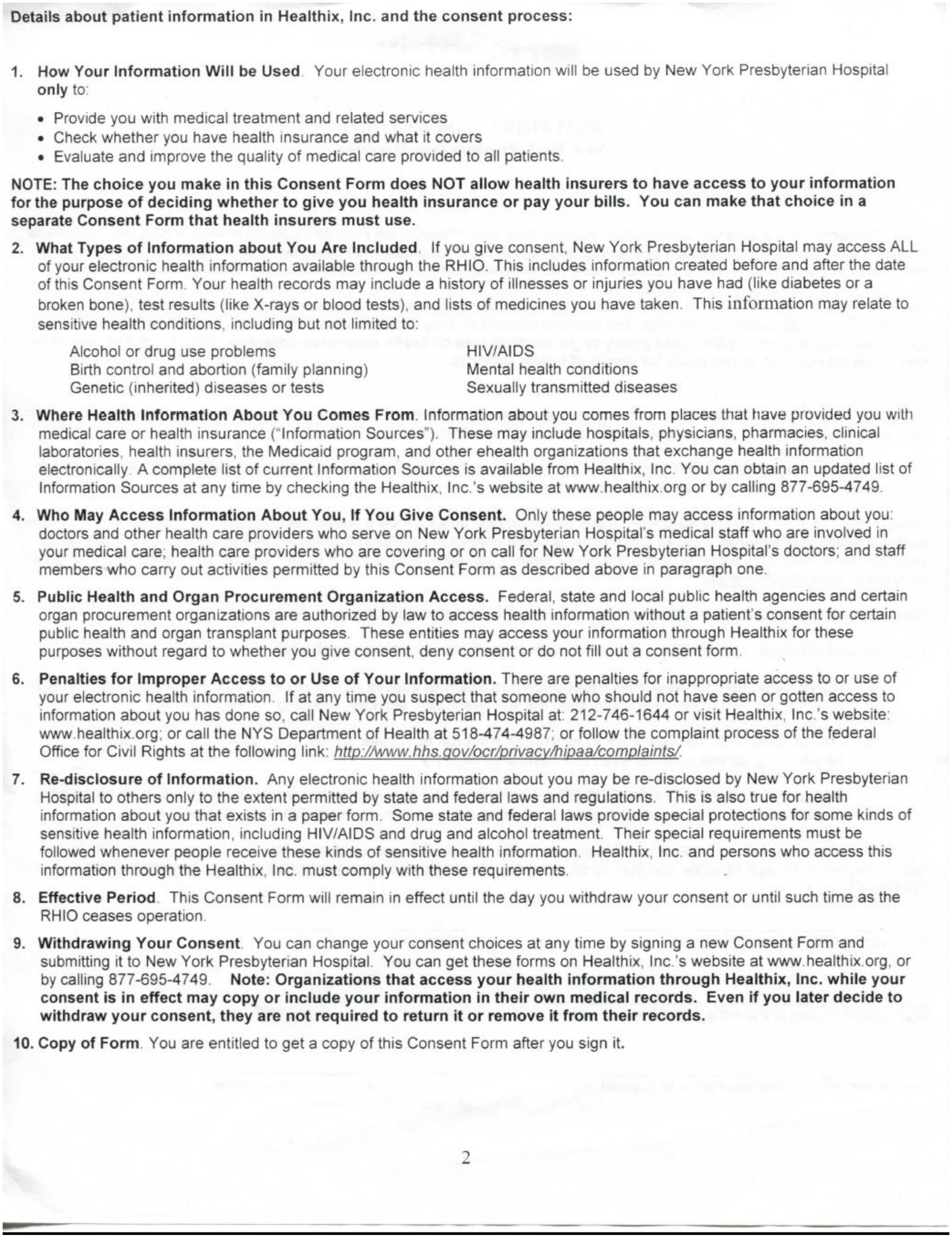
☐ **I GIVE CONSENT for New York Presbyterian Hospital to access ALL of** my electronic health information through Healthix, Inc. in connection with providing me any health care services, including emergency care.

☐ **I DENY CONSENT for New York Presbyterian Hospital to access** my electronic health information through Healthix, Inc. for any purpose, *even in a medical emergency*.

NOTE: UNLESS YOU CHECK THIS BOX, New York State law allows the people treating you in an emergency to get access to your medical records, including records that are available through Healthix, Inc..

If you want to deny consent for all Provider Organizations and Health Plans participating in Healthix to access your electronic health information through Healthix, you may do so by visiting Healthix's website at www.healthix.org or by calling Healthix at 877-695-4749.

Print Name of Patient	Patient Date of Birth
Signature of Patient or Patient's Legal Representative	Date
Print Name of Legal Representative (if applicable)	Relationship of Legal Representative to Patient (if applicable)



Details about patient information in Healthix, Inc. and the consent process:

1. **How Your Information Will be Used**. Your electronic health information will be used by New York Presbyterian Hospital **only** to:
   - Provide you with medical treatment and related services
   - Check whether you have health insurance and what it covers
   - Evaluate and improve the quality of medical care provided to all patients.

NOTE: The choice you make in this Consent Form does NOT allow health insurers to have access to your information for the purpose of deciding whether to give you health insurance or pay your bills. You can make that choice in a separate Consent Form that health insurers must use.

2. **What Types of Information about You Are Included**. If you give consent, New York Presbyterian Hospital may access ALL of your electronic health information available through the RHIO. This includes information created before and after the date of this Consent Form. Your health records may include a history of illnesses or injuries you have had (like diabetes or a broken bone), test results (like X-rays or blood tests), and lists of medicines you have taken. This information may relate to sensitive health conditions, including but not limited to:

   Alcohol or drug use problems
   Birth control and abortion (family planning)
   Genetic (inherited) diseases or tests
   HIV/AIDS
   Mental health conditions
   Sexually transmitted diseases

3. **Where Health Information About You Comes From**. Information about you comes from places that have provided you with medical care or health insurance ("Information Sources"). These may include hospitals, physicians, pharmacies, clinical laboratories, health insurers, the Medicaid program, and other ehealth organizations that exchange health information electronically. A complete list of current Information Sources is available from Healthix, Inc. You can obtain an updated list of Information Sources at any time by checking the Healthix, Inc.'s website at www.healthix.org or by calling 877-695-4749.

4. **Who May Access Information About You, If You Give Consent.** Only these people may access information about you: doctors and other health care providers who serve on New York Presbyterian Hospital's medical staff who are involved in your medical care; health care providers who are covering or on call for New York Presbyterian Hospital's doctors; and staff members who carry out activities permitted by this Consent Form as described above in paragraph one.

5. **Public Health and Organ Procurement Organization Access.** Federal, state and local public health agencies and certain organ procurement organizations are authorized by law to access health information without a patient's consent for certain public health and organ transplant purposes. These entities may access your information through Healthix for these purposes without regard to whether you give consent, deny consent or do not fill out a consent form.

6. **Penalties for Improper Access to or Use of Your Information.** There are penalties for inappropriate access to or use of your electronic health information. If at any time you suspect that someone who should not have seen or gotten access to information about you has done so, call New York Presbyterian Hospital at: 212-746-1644 or visit Healthix, Inc.'s website: www.healthix.org; or call the NYS Department of Health at 518-474-4987; or follow the complaint process of the federal Office for Civil Rights at the following link: *http://www.hhs.gov/ocr/privacy/hipaa/complaints/*.

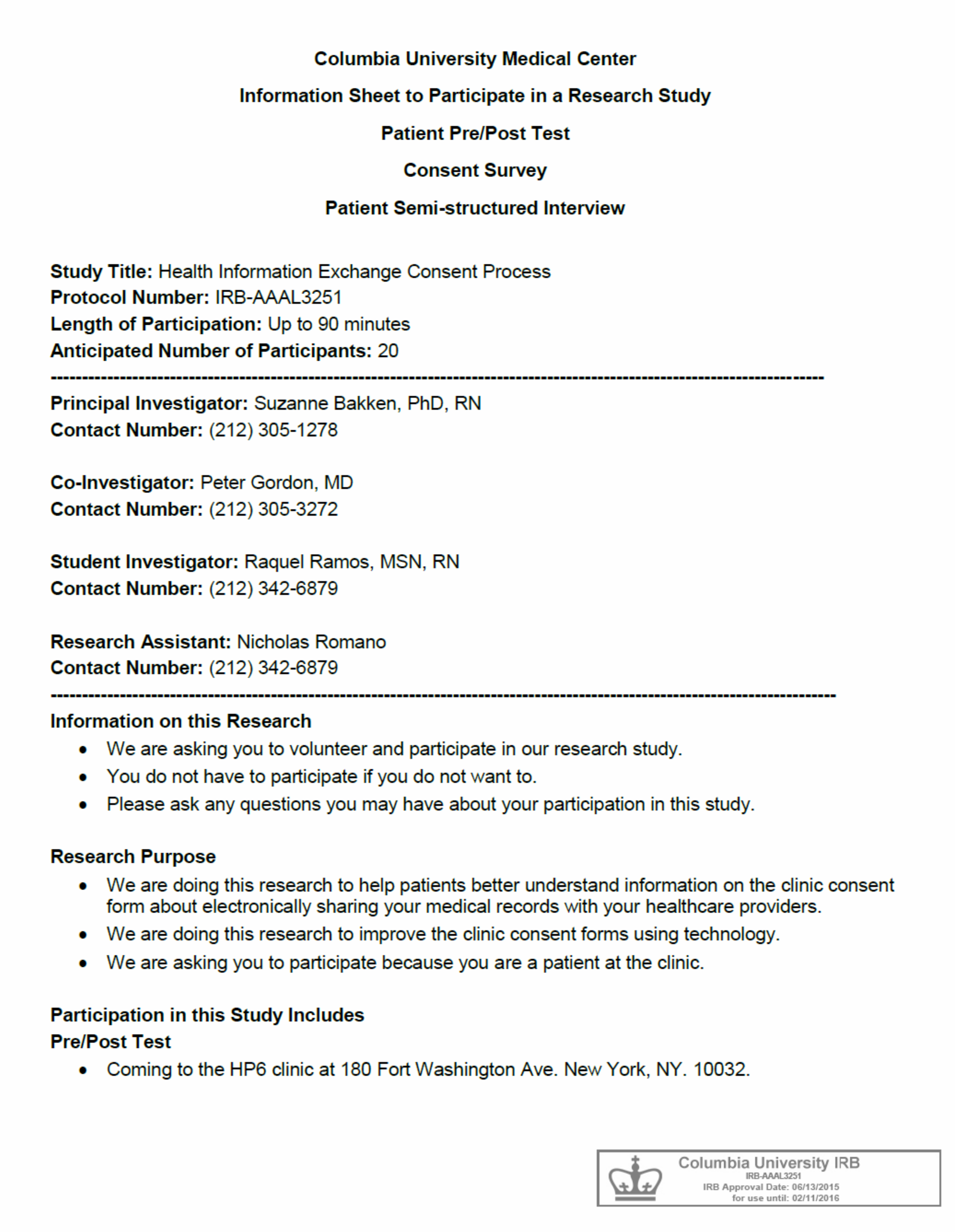
7. **Re-disclosure of Information.** Any electronic health information about you may be re-disclosed by New York Presbyterian Hospital to others only to the extent permitted by state and federal laws and regulations. This is also true for health information about you that exists in a paper form. Some state and federal laws provide special protections for some kinds of sensitive health information, including HIV/AIDS and drug and alcohol treatment. Their special requirements must be followed whenever people receive these kinds of sensitive health information. Healthix, Inc. and persons who access this information through the Healthix, Inc. must comply with these requirements.

8. **Effective Period**. This Consent Form will remain in effect until the day you withdraw your consent or until such time as the RHIO ceases operation.

9. **Withdrawing Your Consent**. You can change your consent choices at any time by signing a new Consent Form and submitting it to New York Presbyterian Hospital. You can get these forms on Healthix, Inc.'s website at www.healthix.org, or by calling 877-695-4749. **Note: Organizations that access your health information through Healthix, Inc. while your consent is in effect may copy or include your information in their own medical records. Even if you later decide to withdraw your consent, they are not required to return it or remove it from their records.**

10. **Copy of Form**. You are entitled to get a copy of this Consent Form after you sign it.

Appendix I: Information Sheet



Columbia University Medical Center

Information Sheet to Participate in a Research Study

Patient Pre/Post Test

Consent Survey

Patient Semi-structured Interview

Study Title: Health Information Exchange Consent Process
Protocol Number: IRB-AAAL3251
Length of Participation: Up to 90 minutes
Anticipated Number of Participants: 20

Principal Investigator: Suzanne Bakken, PhD, RN
Contact Number: (212) 305-1278

Co-Investigator: Peter Gordon, MD
Contact Number: (212) 305-3272

Student Investigator: Raquel Ramos, MSN, RN
Contact Number: (212) 342-6879

Research Assistant: Nicholas Romano
Contact Number: (212) 342-6879

Information on this Research

- We are asking you to volunteer and participate in our research study.
- You do not have to participate if you do not want to.
- Please ask any questions you may have about your participation in this study.

Research Purpose

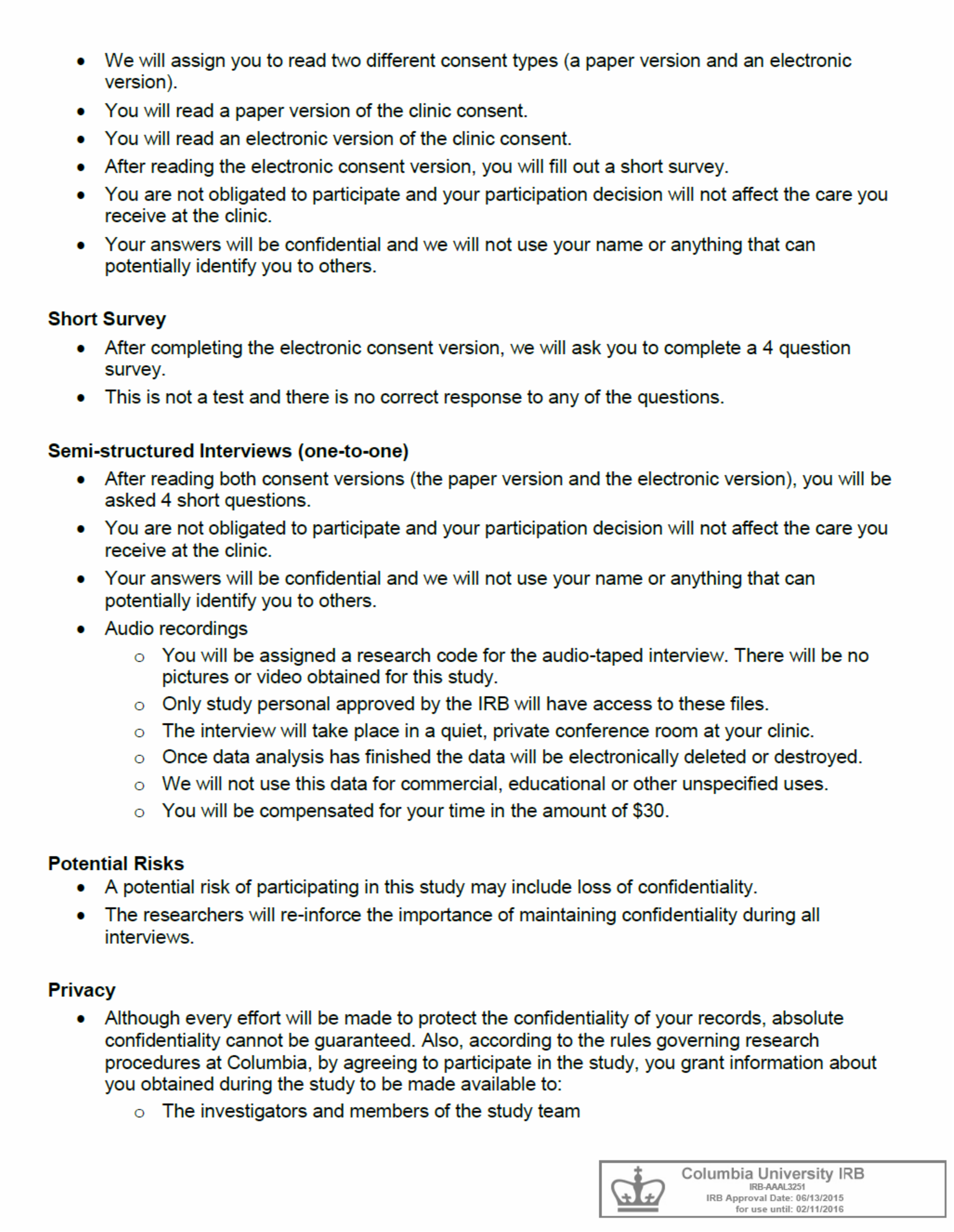
- We are doing this research to help patients better understand information on the clinic consent form about electronically sharing your medical records with your healthcare providers.
- We are doing this research to improve the clinic consent forms using technology.
- We are asking you to participate because you are a patient at the clinic.

Participation in this Study Includes

Pre/Post Test

- Coming to the HP6 clinic at 180 Fort Washington Ave. New York, NY. 10032.

Columbia University IRB
IRB-AAAL3251
IRB Approval Date: 06/13/2015
for use until: 02/11/2016



- We will assign you to read two different consent types (a paper version and an electronic version).
- You will read a paper version of the clinic consent.
- You will read an electronic version of the clinic consent.
- After reading the electronic consent version, you will fill out a short survey.
- You are not obligated to participate and your participation decision will not affect the care you receive at the clinic.
- Your answers will be confidential and we will not use your name or anything that can potentially identify you to others.

Short Survey

- After completing the electronic consent version, we will ask you to complete a 4 question survey.
- This is not a test and there is no correct response to any of the questions.

Semi-structured Interviews (one-to-one)

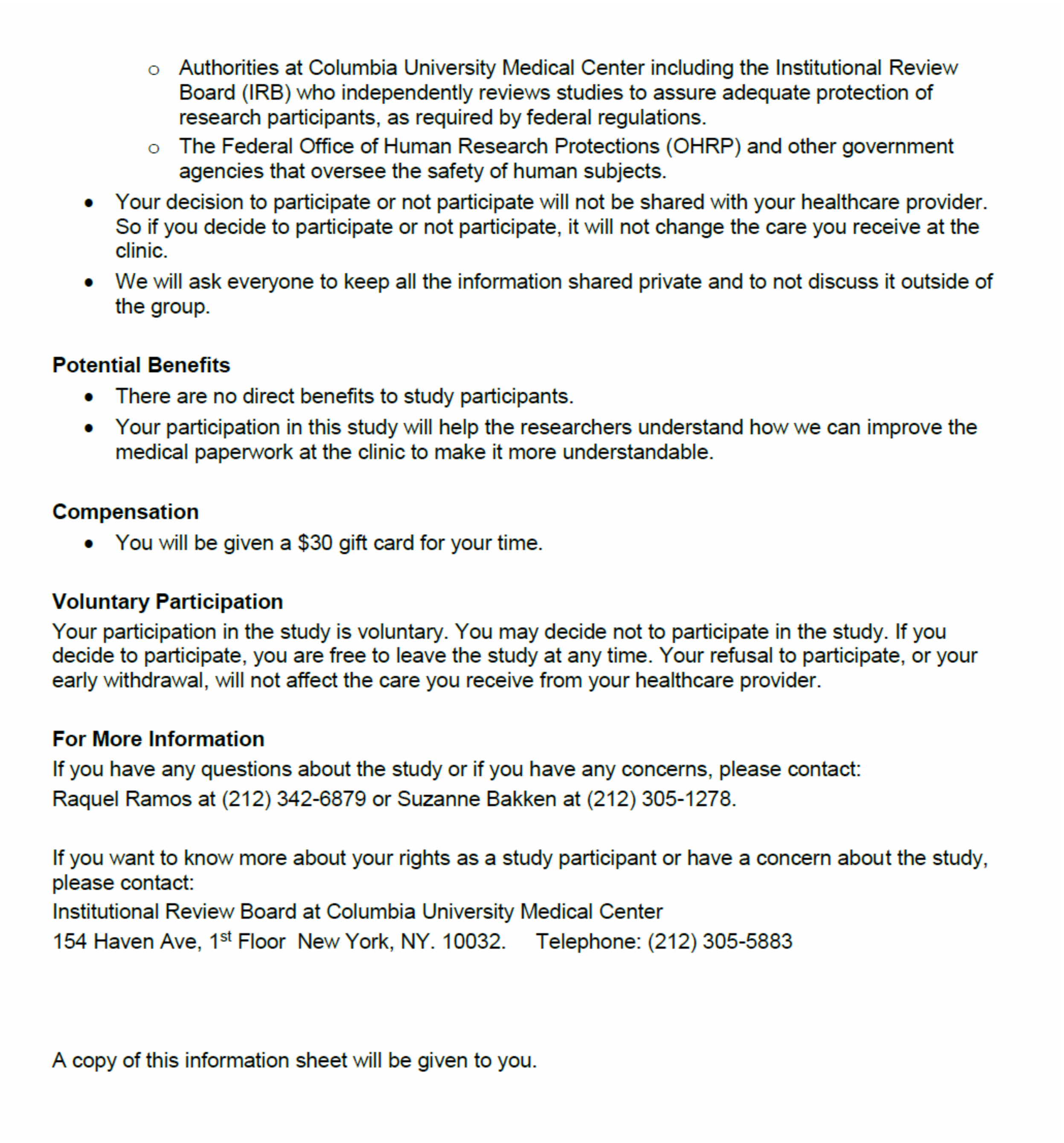
- After reading both consent versions (the paper version and the electronic version), you will be asked 4 short questions.
- You are not obligated to participate and your participation decision will not affect the care you receive at the clinic.
- Your answers will be confidential and we will not use your name or anything that can potentially identify you to others.
- Audio recordings
    - You will be assigned a research code for the audio-taped interview. There will be no pictures or video obtained for this study.
    - Only study personal approved by the IRB will have access to these files.
    - The interview will take place in a quiet, private conference room at your clinic.
    - Once data analysis has finished the data will be electronically deleted or destroyed.
    - We will not use this data for commercial, educational or other unspecified uses.
    - You will be compensated for your time in the amount of $30.

Potential Risks

- A potential risk of participating in this study may include loss of confidentiality.
- The researchers will re-inforce the importance of maintaining confidentiality during all interviews.

Privacy

- Although every effort will be made to protect the confidentiality of your records, absolute confidentiality cannot be guaranteed. Also, according to the rules governing research procedures at Columbia, by agreeing to participate in the study, you grant information about you obtained during the study to be made available to:
    - The investigators and members of the study team



  - Authorities at Columbia University Medical Center including the Institutional Review Board (IRB) who independently reviews studies to assure adequate protection of research participants, as required by federal regulations.
  - The Federal Office of Human Research Protections (OHRP) and other government agencies that oversee the safety of human subjects.
- Your decision to participate or not participate will not be shared with your healthcare provider. So if you decide to participate or not participate, it will not change the care you receive at the clinic.
- We will ask everyone to keep all the information shared private and to not discuss it outside of the group.

Potential Benefits

- There are no direct benefits to study participants.
- Your participation in this study will help the researchers understand how we can improve the medical paperwork at the clinic to make it more understandable.

Compensation

- You will be given a $30 gift card for your time.

Voluntary Participation

Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to leave the study at any time. Your refusal to participate, or your early withdrawal, will not affect the care you receive from your healthcare provider.

For More Information

If you have any questions about the study or if you have any concerns, please contact:
Raquel Ramos at (212) 342-6879 or Suzanne Bakken at (212) 305-1278.

If you want to know more about your rights as a study participant or have a concern about the study, please contact:
Institutional Review Board at Columbia University Medical Center
154 Haven Ave, 1st Floor New York, NY. 10032.   Telephone: (212) 305-5883

A copy of this information sheet will be given to you.

Appendix J: Pertinent Communications

From: Rich Mayer <rich.mayer@psych.ucsb.edu>
Date: August 7, 2015 at 20:45:00 EDT
To: "Ramos-Park, Silvia Raquel" <sr2966@cumc.columbia.edu>
Subject: Re: Permission to use Copyrighted Material

I am glad to have you use my theory. There is no need to ask for permission. Best wishes for a successful research project, Rich Mayer

Sent from my Verizon Wireless 4G LTE DROID

"Ramos-Park, Silvia Raquel" <sr2966@cumc.columbia.edu> wrote:

Dear Mr. Mayer,

Hello. I am completing my doctoral dissertation at the Columbia University School of Nursing. My dissertation is entitled, "Innovative Approaches to Better Inform Persons Living with HIV about Health Information Exchange Using an IPad."
I am requesting your permission to use the Cognitive Theory of Multimedia Learning as part of my dissertation's theoretical framework. Thank you for your time.

Sincerely,

Raquel

From: Fred Davis [FDavis@walton.uark.edu]

Sent: Friday, August 14, 2015 8:24 PM

To: Ramos-Park, Silvia Raquel

Subject: Re: Permission to use copyrighted material

Raquel

You have my permission to use the technology acceptance model as part of your dissertation.

Best wishes

Fred Davis

From: Ramos-Park, Silvia Raquel <sr2966@cumc.columbia.edu>

Sent: Friday, August 7, 2015 9:42 AM

To: Fred Davis

Subject: RE: Permission to use copyrighted material

Dear Mr. Davis,

Hello. I am completing my doctoral dissertation at the Columbia University School of Nursing.

My dissertation is entitled, "Innovative Approaches to Better Inform Persons Living with HIV about Health Information Exchange Using an IPad."

I am requesting your permission to use the Technology Acceptance Model as part of my dissertation's theoretical model. Thank you for your time.

Sincerely,

Raquel

Obtained from: http://www.healthit.gov/newsroom/web-site-disclaimers

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Contact Chartése Day if you have media questions. Your queries will be addressed within one business day.

Go to ONC Speaker Request Form

Get On-the-Ground Support

Email: Chartese.Day@hhs.gov
Telephone: (202) 205-8094
Fax: (202) 690-6079

Last updated: Tuesday, January 15, 2013