Exploring the Future of Informed Consent: Applying a Service Design Approach

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Informed consent is a cornerstone of ethical human subject research. This practice demonstrates the ethical principle of "respect for persons." Our study was designed to imagine an informed consent future, specifically in a digital health context in which informed consent processes are mediated by sociotechnical systems. Design speed-dating workshops were conducted to explore dimensions of the consent communication design space, including social media, interactive quizzes, chat-bots, annotation tools, and virtual learning sessions. To explore both the user experience and how futuristic consent processes might be facilitated, the workshops involved people eligible to participate in digital health research (N=21) and service providers (N=20), including researchers and IRB members. Our findings offer five principles to improve digital informed consent processes: be concise, promote transparency, value time and effort, cultivate trust, and navigate platform risks.

CCS Concepts: • **Human-centered computing → HCI design and evaluation methods**; • **Social and professional topics → Computing / technology policy**.

Additional Key Words and Phrases: research ethics, informed consent, digital health

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1 INTRODUCTION

Traditionally, informed consent to participate in research involves a single touchpoint whereby complex study information is presented via a written consent form. A prospective participant is expected to review the study information and decide whether to participate. The use of online systems to facilitate informed consent in research is becoming standard practice, such as in digital health research, which can involve the use of social media platforms, wearable and remote sensors, and other forms of passive and pervasive data collection [18]. The remote and online nature of some digital health research may further complicate the expectation that consent processes are informing [6, 35, 47, 72]. While informed consent materials are vetted in advance by Institutional Review Boards (IRBs), the peer reviewed literature speaks to problems with consent processes, casting doubts about whether they support prospective participant decision-making about their

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potential involvement in a study [27, 52, 55]. This paper presents findings from an exploratory study that considered the design of touchpoints in futuristic consent processes for digital health research, and their possible unintended consequences.

In Service Design research the term *touchpoint* is used to denote opportunities for people using or participating in a service to make contact with the organization of people and computing systems coordinating the service [69]. Touchpoints are where people find personal support, access specific resources, and gain insights about a service organization by engaging with service providers, throughout their use of the service. In the context of consent processes, touchpoints reflect details about the consent materials, their presentation, and how prospective participants in research are able to engage with content as well as research team members and other people who may help them to make an informed decision.

- **Research Question**: *What are opportunities, barriers, and unintended consequences associated with touchpoints in futuristic informed consent processes?*

To explore this question, our team conducted a series of design speed-dating activities with several futuristic consent processes. Speed-dating in design [78] involves briefly introducing target users to a sequence of imaginative experiences to probe what they might want and need in futuristic scenarios. Applying a Service Design lens we invited forty-one people to participate in the speed-dating, which included prospective participants in digital health research (N=21) as well as "service providers" (N=20) with experience in research and as IRB members. The protocol involved asking participants to imagine their experience using, facilitating, and evaluating each futuristic consent process.[1] To investigate touchpoint design considerations, transcripts from the speed-dating activities were analyzed through multiple rounds of analytic memo writing [5].

The futuristic consent processes reflect a range of ways that existing forms of media could be used to better communicate study content and risk, as well as providing new ways of contacting the study team. These include applying existing technologies, such as the social media platform TikTok and social annotation tools [3], to facilitate informed consent as a *service*, rather than with a single catch-all form. Presented in the Methods (section 3.4), the processes respond to several postulates toward the future of informed consent:

(1) *Building a social media presence.* What if people could follow research teams on social media and join a study directly through social media platforms?
(2) *Presenting in multiple formats.* What if people could choose their own pathway into specific topics with video, audio, visual, and other ways of presenting the consent material?
(3) *Integrating interactive quizzes.* What if people were required to self-assess their own understanding of a study before they are invited to participate?
(4) *Adding definitions in context.* What if people could navigate study details through a series of nested hyperlinks to various topics and levels of detail?
(5) *Estimating time commitment and risk.* What if people could search for studies that match their expectations for participation and risk tolerance?
(6) *Sharing questions and answers.* What if people could review a socially constructed list of frequent questions generated by other prospective participants?
(7) *Hosting virtual learning sessions.* What if chat bots were used to personalize the consent process to meet the learning needs of each prospective participant?

Information technology will continue to advance. While the technologies presented to participants through this study reflect existing forms of media, from a service design perspective we felt that the associated processes capture a range of possible human-computer interaction around

[1]The futuristic processes were developed through a formative study that is detailed in the Methods Section 3.4.

critical touchpoints. As presented in the Findings, we believe that the touchpoints will continue to be relevant opportunities for digital health and Computer Supported Cooperative Work (CSCW) researchers to demonstrate the ethical principle "respect for persons" [2, 26], irrespective of the specific technologies used to communicate study information.

Our analysis identified ten touchpoints where prospective participants and service providers engage with each other and with consent materials. The touchpoints are presented in the Findings as five principles to improve informed consent processes in digital health research. As consent materials are often text heavy, the initial principles raise ways to improve how study details are communicated: *Be concise* (section 4.1) and *Promote transparency* (section 4.2). The later principles raise sociotechnical considerations related to computer-mediated consent processes, including *Value time and effort* (section 4.3), *Cultivate trust* (section 4.4), and *Navigate platform specific risks* (section 4.5). Each section includes a synthesis of recommendations intended for research service providers. Some recommendations can be readily adopted by digital health research, while other touchpoints rely on not-yet-possible technology.

The Discussion section presents practical steps to prepare for futuristic consent processes in digital health. Initial steps include the following:

- Integrate recommended best practices into consent communication design work, whether as tips alongside existing IRB templates or entirely new workflows for launching digital health studies through online recruitment platforms (e.g., Research Match, Prolific).
- Develop guidelines and protocols for moderating information elicited through the course of digital health consent processes. Guidelines should be developed in consultation with professional societies and other stakeholders in academic research.
- Create tools and training programs to help IRB members to evaluate study materials prior to recruitment, as futuristic consent processes may yield complex forms of data.

2 RELATED WORK

This section reviews approaches to designing a consent communication (section 2.1), consent communication in digital health research (section 2.2), as well as Service Design concepts that were operationalized in this study (section 2.3).

2.1 Approaches to designing a consent communication

Digital health research can raise a variety of ethical, legal, and social implications (ELSIs). For health research, ethical implications have traditionally been determined by using accepted principles of biomedical and behavioral research (see Belmont Report [26]). The three principles presented in the Belmont Report include: Respect for Persons, Beneficence, and Justice. Respect for persons is applied in practice via the informed consent process. Beneficence is where the probability and magnitude of potential harm that a research participant may experience is considered against the ability to mitigate harms and the value of knowledge to be gained from conducting the research. The principle of Justice speaks to minimizing the burden of research on a particular group or population and including those in research who are most likely to benefit from the knowledge produced. In 2012, those principles were applied to research involving information and communication technologies (see Menlo Report [2]). The Menlo Report added a fourth principle labeled "respect for law and public interest" to capture how technologies, including algorithms needed to be considered beyond the individual level, which is traditionally how research subject rights are evaluated.

In addition to the development of ethical principles, federally funded health research is regulated by the US Federal Policy for the Protection of Human Subjects (referred to as the "Common Rule").[2]

[2]US Code of Federal Regulations, Title 46 Subtitle A-A Part 46: *Protection of Human Subjects*

The US Common Rule outlines expectations for organizations that receive federal funding and conduct research involving human participants. Included are expectations for researchers to provide people with an opportunity to make an informed decision about whether they want to participate in research (US Federal Code §46.116(a)(5), updated January 21, 2019):

> "**(i)** Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."
>
> "**(ii)** Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate."

Consent form templates that are developed by IRBs serve as a guide for researchers to develop a written consent document that is compliant with federal regulations. The template informs researchers about required content noted in the Common Rule (§46.116). Consent templates map this content to standard headings (e.g., purpose, procedures, risks, benefits, etc.) and who to call with questions or to report problems. Consent templates also conclude with a signature line to document that the person who is joining the study has been provided with the content and has had an opportunity to ask questions about the study. The guidance provides researchers with instruction for font size and reading level; however, does not educate the researcher about how and why they may need to tailor the consent communication to prospective participants. While consent templates are intended to serve as a support tool, they prompt researchers to format the consent communication as a structured document.

Many researchers have recognized the need to improve the consent process. Previous research has explored how choice of language [60], visual content [57], and interactive features [3], may promote specific values in an informed consent process, such as understanding [9, 14, 56], reading time [46, 57], and trust [57], and specifically among vulnerable or at-risk populations [47, 56]. See Bloss et al. [6] for an analysis of existing IRB processes and five ideas to enhance research protections. As the field of digital health research continues to advance, it is likely that informed consent will become an interaction between prospective participants and a computing system. For example, the *mPower* clinical observational studies about Parkinson disease were conducted purely through an iPhone [7, 16]. The need to make study information accessible by addressing barriers such as digital literacy is critical [47, 56].

However, some novel technologies may be too challenging for people to fully grasp, such as machine learning and artificial intelligence. The complexity of this technology raises an important concern about whether prospective participants can be fully informed in digital health studies that involve machine learning and artificial intelligence [4, 54].[3] To address this concern, Pickering et al. [54] proposes a trust-based alternative to informed consent, in which trust refers to:

> "*... the willingness of a party to be vulnerable to the actions of another party based on the expectation that the other will perform a particular action important to the trustor, irrespective of the ability to monitor or control that other party*" [54, pg. 10].[4]

[3]Researchers, IRB members, and funding agencies, among other stakeholders, may not fully grasp the personal and societal risks associated with an advanced technology. Bernstein et al. [4] presents an approach to generate a list of potential unintended consequences for technology research through an Ethics and Society Review (ESR) process.
[4]See Mayer et al. [41] and Cook et al. [12] for definitions of organizational trust.

Following this definition, a trust-based approach would involve cultivating "trust in the researchers and their intentions" for a study [54, pg. 13]. In practice, a trust-based approach would refocus the consent process from simply providing legally required study information to promoting dialogue among researchers and prospective participants about the known and uncertain risks associated with study participation. The ethics review process would also shift under a trust-based approach, from whether consent materials comply with certain legal standards to whether researchers and prospective participants are able to engage with each other "... on an equal footing and sharing the risks of failure" as partners in research [54, pg. 13].

2.2 Consent communication in digital health research

Communicating details about digital health research can be challenging. Digital health research can involve people with diverse backgrounds and in novel situations with technology, which means that people joining these studies need a fundamental understanding of the research, the technology being used, and the volume and granularity of data being collected [50]. Consent materials are not easy for people to understand [9] and prospective participants often fail to ask critical questions [74]. To improve comprehension, Willis [76] recommends researchers apply *cognitive interviewing* techniques to pretest study materials with people who are eligible to participate. A cognitive interview involves an intensive probing of how people think about content, in order to learn about their thought processes and points of confusion. These steps can be valuable when tailoring the consent communication for particular populations [1].

Community-based health research requires more attention. Researchers who work with people in resource limited communities are encouraged to consider the larger "cultural" settings that particular ethnic and social groups exist within [39]. For instance, Nebeker et al. [51] report findings from a survey-based study involving people from communities historically underrepresented in biomedical research (e.g., Latino, Somali, Native Hawaiian Pacific Islander) that identify critical literacy gaps, related to the informed consent and data management processes, that limit participation in digital health research. Researchers should consider ways of involving people from a community as partners in research. For example, Silka et al. [62] present a case study of a community-based participatory effort to create guidelines for mutually beneficial research partnerships within a region. Research with participant communities that are entirely online (e.g., patient support forums [37]), involve similar considerations for respect and recognition of power, as well as self-presentation and privacy throughout the conduct of research [10, 44, 72].

As some digital health studies, such as research about patient support forums [37], may involve people from various regional areas, researchers may need to consider geopolitical differences in human-subject protection. For example, a telemedicine study conducted in the USA, but involving people from the European Union (EU) would need to comply with the General Data Protection Regulation (GDPR), by accounting for "the right to be forgotten" (GDPR Article 17§2) among other provisions guaranteed for EU residents. Digital health devices are also used to collect data for machine learning and artificial intelligence research, in which the specific purposes for the data may be less clear when the data is being collected—even for the research team. In these cases, researchers may choose to obtain *broad consent* for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, rather than update/amend a *study specific consent* as researchers identify new uses for the data [36].

Novel technologies are used in some digital health studies, including internet connected devices, wearable and embedded sensors, and augmented reality experiences [18]. The risks associated with these technologies can be challenging to explain [23]. To address this concern, Luger and Rodden [35] recommend three principles to enhance the informed consent process, in the context of ubiquitous and pervasive computing systems (Ubicomp): (1) enable participants to review/withdraw

their consent and data at any point during and after a study, (2) provide visualizations and other "scaffolds" to help people understand how their data flows through a study system and third parties, and (3) enable users to make fine-grained choices about the ongoing use of their data in the study. These guidelines for Ubicomp research promote a view of consent processes that are ongoing and dynamic, but also require new technological infrastructure to facilitate [28].

2.3 Applying service design as an analytic lens

Improving consent processes largely depends on the work of research teams and IRB members, referred to in this study as "service providers." Service Design [69] concepts stem from a framework presented by Star and Strauss [65] for analyzing the less visible work that people perform to facilitate such organizational services. The framework describes the personal performance involved with facilitating an organizational service as occurring visibly on the *frontstage* for an audience and on a *backstage* that may only be visible to the performer and anyone close by as they prepare to perform (e.g., coaches, family, friends).[5] For example, the results of academic research may be reported on various frontstages, including journals, symposiums, and inline citations, but people on the backstage of research, such as students and administrative staff, may not be acknowledged for their important, yet less visible work.

In a human-computer interaction (HCI) context, backstage work can involve coordinating with computing systems, which can further obscure roles played by people [65]. As an example, crowdsourcing systems involve coordinating people to perform complex work, such as creative writing, through a sequence of short and simple tasks [19]; however, crowdsourcing platforms can perpetuate power asymmetries between people who perform and request crowd work [43].[6] To address this concern, Vlachokyriakos et al. [73] discuss how *Service Design* [69] offers a framework for developing sustainable and collaborative infrastructure(s) for delivering services that care for backstage staff. Presenting a case study of a solidarity clinic where hundreds of volunteers and doctors provided free primary medical care and medications to thousands of people, Vlachokyriakos et al. [73] discuss how communication technologies play into organizational decision-making as well as caring for clinic staff suffering burnout. Service Design takes a human-centered approach to create infrastructure(s) that respond to the needs of people on a backstage [69].

There can be multiple audiences to account for in a Service Design plan. For example, design considerations for a government sponsored health care service may primarily support people using the service to find medical attention; however, the service may also need to account for the regulatory, fiduciary, and other needs of government stakeholders providing for the service [32]. In e-Government system design, this tension between the needs of service recipients and government stakeholders can result in design decisions that are not always human-centered for recipients [32]. The research consent process may suffer from a similar design tension. As research organizations strive to meet the requirements outlined by the US Federal Common Rule, the focus becomes compliance with the "letter of the law" over a consent process that may be more accessible and, subsequently, more ethical.

The typical consent process may involve only a few "touchpoints" where people on the frontstage make contact with service providers on the backstage [69], such as researchers and IRB members. Typical touchpoints in the consent process include, for example, responding to an interest survey, inviting prospective participants to review a consent form, answering participant questions, corresponding with an IRB about problematic events, safely removing participants from a study, and returning results to participants after the study concludes. Contact between prospective participants

[5]See also Goffman [20]'s characterization of personal performance.

[6]See McInnis and Leshed [44] for ethical considerations in HCI research involving crowd workers.

and service providers at a touchpoint may involve personal communication and props, like prior results and legal guidelines, as well as processes, such as tutorials on using a digital health device. Our study applied Service Design concepts to identify possible touchpoints in futuristic consent processes, and then studied the opportunities, barriers, and potential unintended consequences from the perspective of people on the frontstage of a digital health research experience, as well as those performing on the backstage.

3 METHOD

3.1 Recruitment

In total, forty-one people agreed to participate in the study. All participants were recruited through a prior study involving child health monitoring devices, such as crib mounted physical activity sensors. *Prospective participants* included mothers of childbearing age, who were recruited through a variety of sources, including Research Match, a local women's health center, as well as a text message service that provides regional information about access to healthy and affordable food options, primarily serving Spanish speaking households (51.2%, N=21).

In addition to recruiting people who are prospective participants in digital health research, the study also involved participants with experience conducting and evaluating digital health research (referred to as "service providers"). *Service providers* (48.8%, N=20) recruited to participate in the study included one person with general research experience, thirteen people with experience as digital health researchers, and six people with experience serving as IRB members. Service providers were contacted through professional associations, including the Digital Medicine Society (DiMe), Public Responsibility in Medicine and Research (PRIM&R), and the Healthy Brain and Child Development consortium (HBCD). All participants received $50 for participation.

3.2 Procedures

To explore considerations related to the design of touchpoints in futuristic consent processes, our research applied a service design approach, which involved multiple rounds of design speed-dating with prospective participants as well as service providers [78]. Design speed-dating enables researchers to elicit feelings and perspectives about possible design futures from likely target users. Specifically, the designers generate several concepts based on different futures for a given design space, and then recruit likely target users as participants to sample that design space, by reviewing each concept in rapid succession. To promote reflection, design teams ask participants to critically reflect on what they might be willing to use or do in the context of each concept, so as to probe what they need, want, or do not want. By rapidly exposing target users to the concepts, speed-dating in design can also help designers to recognize cases in which possible solutions unintentionally yield ethical, legal, or social consequences. Zimmerman and Forlizzi [78] argue that unlike traditional fieldwork, "speed-dating experiences often yield insights that allow designers to reframe problems and situations by revealing latent user needs or desires" [78, pg. 31].

For our study, each design speed-dating session involved seven concept ideas, lasted 90-minutes, and included the following stages: Team introduction (2-minutes), presentation of related research (5-10 minutes), challenges and possible risks with the standard consent process (5-minutes), presentation and discussion of each idea (5-10 minutes per idea, max 65 minutes), semi-structured discussion about general observations (remaining ~10 minutes). The sessions were conducted via online video conferencing with prospective participants in February 2022 (4 sessions) and service providers in March 2022 (5 sessions).

Prospective participants in research were invited to consider their possible user "journey" through each consent process, while service providers were asked to consider how they might facilitate and

evaluate each consent process. Online polling questions were used to prompt conversation about each idea.[7] The questions included:

- Which of the following best describes your motivation to use this service/resource?
- To what extent do you agree or disagree with the following statement: "I imagine that most people would learn to use this communication option very quickly."
- To what extent do you agree or disagree with the following statement: "I imagine that most researchers working with human subjects would want to add this communication option to their informed consent process."

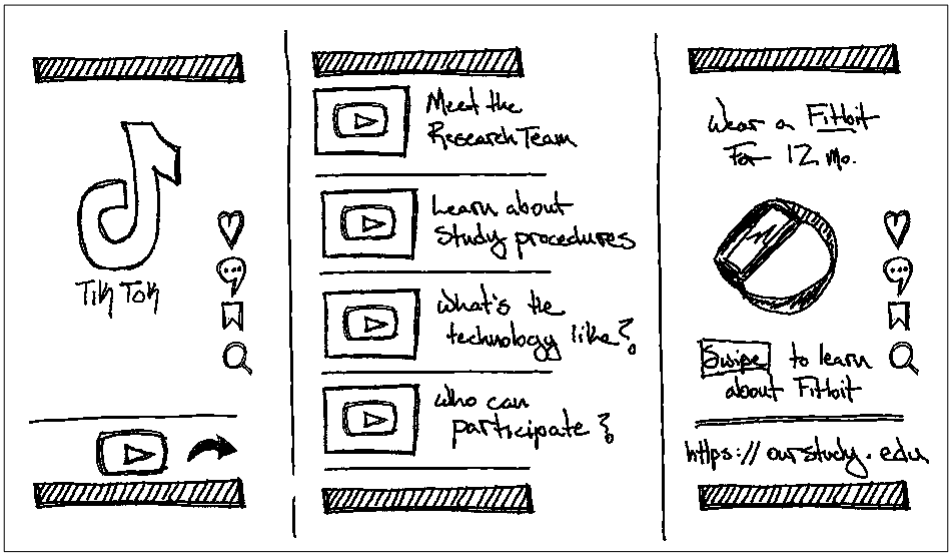

Fig. 1. Lo-fidelity notional sketches used to present *Idea #1: Building a social media presence.* The sketch depicts a TikTok account created by a digital health research team to communicate information about an opportunity to participate in research. The account would include a library of short 30-second videos as well as instructions on how to connect with the research team with direct messages on TikTok or through the study website.

Lo-fidelity depictions of the ideas were used (e.g., sketches, notional graphics), so as to focus participants on concepts, rather than specific decisions in a hi-fidelity prototype (see example Figure 1). Each of the futuristic consent processes were generated through a formative study involving prospective participants in digital health research and are presented in terms of existing related work (Section 3.4), so as to highlight known opportunities, barriers, and possible unintended consequences associated with their use in consent processes.

After the design speed-dating rounds, polling questions were again used to elicit reflection about the possible futures [78]. The participants were prompted to reflect on the design space in terms of several dimensions, including usability, understanding study details, and feelings of trust in research. The poll questions included:

- Which (if any) of the ideas to improve the consent process feel ...
  - the MOST USEFUL to participants?
  - the MOST USEFUL to researchers?

[7]Due to technical difficulties with the video conferencing system, we were unable to analyze the polling results.

  - likely to be approved for use by IRB members?
  - likely to INCREASE your trust in the research team?
- Where do you see the greatest potential for confusion?

Participants were presented with the poll results to prompt conversation about their similar and different perspectives on the futuristic consent processes.

3.3 Analytic memo writing

Audio from each session was machine transcribed into 2,205 participant statements (average 245 per session). Statements from the transcripts were analyzed through multiple rounds of analytic memo writing [5] conducted by four members of the research team. Analytic memo writing is a qualitative analysis method used to identify values, roles, and processes in social and technical systems, such as online community content moderation [42]. The analytic memo writing lasted approximately 6-weeks and involved each member of the team independently reviewing the transcripts to identify statements about possible touchpoints.

Stickdorn and Schneider [69] definition of "touchpoints" in service design provided a guide for our analysis. In the context of digital health research, touchpoints may include prospective participant interaction with static or dynamic consent materials prepared by service providers as well as direct communication with service providers, whether synchronously or asynchronously. For each identified touchpoint, analytic memos were written to capture considerations related to the touchpoint design, such as issues related to usability, understanding study details, and feelings of trust in research. The team met weekly to discuss touchpoints, by reviewing statements in the memos and emergent themes in the analysis.

The Findings present our analysis in terms of five principles to improve consent processes: *Be concise* (section 4.1), *Promote transparency* (section 4.2), *Value time and effort* (section 4.3), *Cultivate trust* (section 4.4), and *Navigate platform specific risks* (section 4.5).

3.4 Formative study to develop futuristic consent processes

The futuristic consent processes were developed through a prior focus-group based study. The prior study was conducted in September 2021 via online video conferencing. Participants included mothers of childbearing age (N=19). For the focus group discussions, participants were presented information about a digital health technology that uses a wearable sensor to collect biological and behavioral data (e.g., heart rate, location, physical activity) and deliver just-in-time notifications via the wearable during periods of physical inactivity among people. The intended technology users were mothers and child caregivers. In total, the prior study involved four focus groups, each with 4-7 participants and lasting 60 minutes.

Statements from the focus group transcripts were analyzed through an affinity diagramming process [24] (N=204 statements). Affinity diagramming is a highly structured qualitative process that involves regular group deliberation to generate a hierarchical organization of themes from raw data. The themes were used to construct futuristic consent processes. Four members of the research team independently generated 20 initial ideas, which were then consolidated through deliberation into seven ideas reflecting a broad range of futuristic consent processes.

In the sections that follow, related work is used to describe each idea, so as to present known considerations that may affect usability, understanding, and feelings of trust during an informed consent process. The consent processes are referred to throughout the Findings by Idea number and title (Section 4).

3.4.1 Idea 1: Building a social media presence. Social media platforms are a common recruitment tool for digital health research. Social media can be leveraged to reach highly specific populations,

making these platforms an invaluable tool for research involving communities of people who are loosely connected, globally distributed, or difficult to reach locally.[8] However, it is less clear whether social media companies may use ancillary data associated with research consent processes that occur on their platform [49]. Curtis [13] identified three main risks associated with recruiting research participants via social media platforms: (1) limited resources for confidentiality, (2) insufficient privacy protections, and (3) the potential to divulge protected health information about prospective participants. *What if people could follow and join research through social media?*

Design. To explore participant perspectives around social media-based experiences of consent material, prior research developed the "Building a social media presence" idea (Figure 1). The idea involved using *TikTok* to present short informative videos about a study and to introduce the research team. Prospective participants could "swipe" a video to reveal additional information and links to the study website. Participants would also be able to use the direct message features to communicate with members of the research team, if they had questions or wanted to join the research. As a study progresses, the social nature of TikTok could help participants to follow along and form community with each other. During the design speed-dating participants asked us to clarify whether the process "would be like paid advertising for recruitment?" (P5). We responded by suggesting that researchers might create a shared account on TikTok for their study or organization, in the same way that many research labs maintain a social media presence.

3.4.2 Idea 2: Presenting in multiple formats. Rather than require people to follow a linear path through materials, such as reading them from top to bottom, online learning platforms enable students to search for lessons that interest them. Online learning platforms incorporate a mix of media types, from short summaries to audio and video clips; such alternative formats can benefit historically marginalized groups in research [56]. *What if people could choose their own pathway into consent materials, similar to how people navigate an online learning platform?*

Design. To explore a multi-modal approach to the consent process, prior research developed the "Presenting in multiple formats" idea. The idea resembles what Kross and Guo [33] characterize as learning technologies to promote global access to materials and equity through one-to-many individual interactions [33, Table 1, pg. 2]. The futuristic process would enable participants to click into lessons associated with components of a study, where they could read short summaries, watch videos, and follow links for more details. Providing images and video may be preferred by prospective participants [56], as visuals can help draw attention to study concerns, like potential privacy risks [57]. The online platform would also be used to officially consent participants. After volunteering, participants could use the platform to review consent materials, find study updates, and access study data. Participants did not have any clarifying questions about this idea during the design speed-dating.

3.4.3 Idea 3: Integrating interactive quizzes. A common concern is that prospective participants in research do not fully understand key components of consent materials. McNutt et al. [46] found in two separate studies of prospective research participants that most people took less than half the expected time to read consent materials, which indicates a high propensity to selectively scan content. Interactive online quizzes can provide an opportunity to assess understanding, while providing factual information in response to incorrect answers. Klitzman [30] offers several considerations when integrating quizzes into consent processes, including how to avoid rote memorization, quiz timing, and whether quizzes should be repeated after a study begins. As an example, the *All of Us* digital health research program [15], which involved wearable sensors to learn about biology, lifestyle, and environmental effects on health, incorporated quizzes in the

[8] See Hallinan et al. [22] for a discussion about the promise and perils of large-scale research involving social media platforms.

consent process. When prospective participants responded incorrectly to a quiz item, the system would recommend relevant sections to review. *What if people had to assess their understanding of a study, before they are permitted to participate?*

Design. To explore embedding quizzes into consent materials, prior research created the "Integrating interactive quizzes" idea. We imagined that 10-15 quiz questions would be embedded at the end of an online consent form, just before participants indicate whether they want to volunteer for a study. The quiz questions would be based on material in the consent form. While the quiz questions would be optional, they could be written to elicit interest. During the design speed-dating activity, participants were curious about the user interface design, specifically the flow from the consent material to the quiz: "Would you have the quiz pop up in a new window, [...] or right at the bottom of the consent?" (P5). We responded by saying that the quiz was not meant to be a test, so people would not be prevented from rereading to find answers.

3.4.4 Idea 4: Adding definitions in context. Wikipedia is a vast knowledge network. Each article links to others within and beyond Wikipedia, making it possible for people to navigate through a breadth of topics. Thousands of articles on the Wikipedia platform are translated into a wide range of languages, making this knowledge available to people around the world. *What if people could "click" in to review additional study details, examples, analogies, etc.?*

Design. To explore how a knowledge network, like Wikipedia, might be used to enhance the research consent process, prior research developed the "Adding definitions in context" idea. Similar to how publishing templates in Wikipedia can be used to collaboratively author articles [21], research teams could use publishing templates to share their experience with specific study technologies, techniques, and mitigating study related risks. The idea we presented during the design speed-dating would enable people to review the consent materials in a language of their choice and use hyperlinks to navigate various topics, such as study technology, techniques, and how to navigate various risks related to research. During the design speed-dating activities, participants asked us about the translation process: "Were you thinking about automated language translation or literally providing a couple popular languages, depending on the audience?" (R34). We responded that the materials should probably be translated and reviewed by experts.

3.4.5 Idea 5: Estimating time commitment and risk. The Google Play Store is a popular way for people to find digital health services [45, 70]; however, consumer protections related to these services are limited, as App reviews by experts are inconsistent [11] and data privacy statements do not always reflect data management practices [25]. In an experiment involving research data disclosure statements, Rudnicka et al. [60] found that when primed with messages that promote "learning" as a purpose for research, people are more likely to disclose private data despite showing general alertness about the types of data they are disclosing. *What if people could use a study marketplace, similar to the Google Play App Store, to search for study opportunities that match their personal preferences for risk, commitment, and other factors?*

Design. To explore the idea of a digital health study "marketplace" designed to prioritize the protection of research participants, prior research developed the "Estimating time commitment and risk" idea. As presented during the design speed-dating activities, the idea would involve a common platform that people could use to find opportunities to participate in digital health research, like Research Match and Prolific. People would be able to filter for specific data privacy protections and synchronize their personal calendars with the service to evaluate how study expectations might play into their daily lives. Additionally, the platform would assist people in downloading, installing, and uninstalling any study related services from personal devices (e.g., smartphones, smart speakers). During the design speed-dating activities a participant wondered: "Who's paying

for this App Marketplace to exist and how many other institutions have bought into it?" (P9). We offered that it might be a community-based initiative.

3.4.6 Idea 6: Sharing questions and answers. A list of Frequently Asked Questions (FAQ) can be a valuable resource for people when they are just learning about a study, but writing a list of FAQs takes time. Additionally, it is hard to know what the FAQs are without asking participants and hearing their questions and concerns. One solution is to delegate some informed consent decisions to trustworthy people, who are competent, moral, and act with good intentions [53]. Another solution is to crowd-source FAQs with prospective participants [3]. Balestra et al. [3] experimentally evaluated a crowdsourcing-based model to collaboratively review consent materials with social annotation tools. *What if people could review and add to a socially constructed list of frequently asked questions (FAQs)?*

Design. To revisit design considerations related to social annotation systems in research consent processes [3], prior research developed the "Sharing questions and answers" idea. As presented in the design speed-dating activities, the idea would involve a system similar to standard commenting features in document processing platforms, like Microsoft Word; however, instead of leaving a comment, participants would be prompted to share a question about highlighted section(s) of the consent materials. The questions would be shared directly with members of the research team who would respond with answers. As questions and answers accumulate, the system would automatically synthesize the responses into an FAQ for the study, similar to how the crowdsourcing platform *Storia* [29] can synthesize question-and-answer pairs about an event reported in social media into a summary article and timeline. Participants had no clarifying questions about this idea.

3.4.7 Idea 7: Hosting virtual learning sessions. In some large scale digital health studies, engaging with every participant can be a daunting task for researchers. *Town Hall* style forums [38] to discuss research with prospective participants can prompt participants to review materials and prepare questions [40]; however, people may have limited time, lack access to transportation, childcare, among other barriers to participation. Additionally, choosing to participate in a town hall may introduce privacy risks for people who might be eligible because they have a condition. As an alternative, chat bots are commonly used to help people navigate online resources, find answers, and connect with representatives for personalized assistance. Chat bots typically follow a script, but some use natural language processing methods to suggest relevant answers. *What if chat bots were used to personalize the consent process?*

Design. To explore how chat bots might help researchers to facilitate consent processes in large online studies, prior research developed the "Hosting virtual learning sessions" idea. The idea is reminiscent of the Torous et al. [70] proposal for automated systems (or "digital navigators"), to help people filter through available digital mental health services on App Stores. The idea would involve participants corresponding with a chat bot throughout the informed consent process. The chat bot could recommend common responses based on participant questions about the study and could perform study specific tasks, such as reviewing potential risks. For more complex responses, the chat bot could provide support scheduling a group video conference with members of the research team. When ready to volunteer to participate for the study, the chat bot could validate a digital signature. During the activity, a participant shared: "I only like chat bots if you can also get a live person" (P40). Otherwise, participants did not ask clarifying questions.

4 FINDINGS

Based on an analysis of design speed-dating activities involving the futuristic consent processes (Section 3.4), the Findings are presented in terms of five principles to improve consent processes in digital health. Our team randomly assigned participants in the study to the following unique

identifier ranges: Prospective participants are identified as P1-P19 and P40-P41, researchers are identified by the ID format "R#" (e.g., R21), and people with experience as IRB members are identified with the ID format "I#" (e.g., I20).

4.1 Be concise

Researchers use guidelines, templates, and examples provided by local IRBs as they develop informed consent procedures. "Researchers, I think are often in favor of using written consent forms, because it's what they know Institutional Review Boards like [...] do I think these are usable or engaging or that people are typically processing everything that's in it. No, not really" (R23).

Prospective participants in research feel that a consent process does not necessarily need to be an engaging experience, but it must promote understanding. "Whoever is writing [the consent materials] on the research side [needs to be] able to put themselves in our shoes. So what it comes down to, all the stuff that we've talked about, from the quizzes to the social media little videos, to this: it's really a test to see if you can explain this to a five year old" (P9).

4.1.1 Touchpoint #1: Communicating clearly with text. Participants raised many criticisms about the lack of plain language in standard consent materials. For prospective participants, reading these documents can take a lot of time, because the "format sometimes is just like a lot of words on you know multiple pages" (P5). These formatting decisions can even make reading consent materials strenuous, for example, "reading small font on a screen [...] actually does cause like physical pains, headaches" (P9). These are important factors to consider, because if people do not feel comfortable with a study and struggle to understand the material, then they may opt out, as "not everyone has the time or energy to want to follow up to clarify; a lot of people will drop off" (P9).

Service providers raised similar concerns, "if it's too long, and they're not reading it, it's not serving its purpose" (I38). Local IRBs may require specific legal language that add to the length, making a consent process feel more contractual than educational, "like, a mortgage contract where it's just blah blah blah" (P19). The legal language can raise concerns, "the institution is saying this is required language that has to be there [but] it can sound scary to people" (R27). A researcher recommended, "[I]f these [consent materials] provide, if not a definition, but like an example of something, like [...] *if your data got out, we would notify you.* Something like that would be more contextual [and] a value add, rather than just kind of defining the terms" (R31).

Service providers raised that due to the legal significance of some required text, academic organizations may be resistant to moving away from standard consent templates. For example, a "hospital or the university itself might be concerned that there are potential loopholes legally that they might expose themselves to by having a kind of informal consent [process]" (R26). While prospective participants and service providers recognize the need to communicate study details concisely, the legal weight of some required text can be an institutional barrier to change.

4.1.2 Touchpoint #2: Providing for multiple learning styles. Many participants said that they want researchers to move beyond text-based consent processes, but doing so may introduce new challenges. For example, prospective participants suggested that short video-based consent processes would be useful, and they could see themselves, "clicking those links and watching videos" (P11); however, other participants raised navigational concerns, "it could potentially take me 15 minutes to watch all these videos, whereas reading and or skimming through this document, especially for certain sections, [maybe] two minutes" (P9). Additionally, people may not pause to reflect as much, "like the pace and speed and like review-ability [matter], because it's pretty easy for stuff to just like keep running on one's phone" (R23). A few participants felt that the video style could affect their trust in the research, "I would be hesitant to use TikTok, [to review study] information [...] I'd be skeptical that all the details were provided in a video format" (P12).

Service providers felt that they may not have the skills to create the learning experiences depicted in the futuristic consent processes. "Researchers would love there to be tools and templates, [but] it's presuming a lot of skill sets researchers may not have" (I38). Several researchers shared their experience using online learning modules in consent processes, "I've been working on offering the components of what you can find on a standard consent form within kind of an e-learning module [...] but, that's not something that we fully use [in all studies]" (R30).

Interactive consent processes may also generate a lot of content, which would need monitoring. In consent processes that involve high levels of participant engagement, like *Sharing questions and answers* (Section 3.4.6), version control may be critical for monitoring what content people are presented (or exposed to) as new questions and answers are added to the FAQ over time. "What version of this are participants signing? As you refine [the FAQ list], how many versions do you have and which have participants seen? It could create a record keeping challenge" (I38). Online platforms can provide people with various ways to access consent materials; however, facilitating such access may be challenging for researchers.

IRB members wondered about how information that bubbles up during a consent process might be recorded. "If you change one thing [about the consent communication], how many other things do you need to modify? It is what I call the three C's: Consistency, Clarity, and Compliance" (I38). This was echoed by others, "if you have multiple places where the information is described, then if you change one you have to make sure that it's consistent throughout, and so there's a risk of missing an update to the website, [for example]" (I25). Online systems can facilitate novel learning experiences around consent materials, but monitoring these experiences can be challenging.

4.1.3 Summary. Being concise involves making sure a consent communication is clear and relevant, whether in text, video, or other formats. People new to research may feel intimidated by terms, like confidentiality. Providing relevant examples of how researchers will respond to situations involving the terms can help people understand their meaning. Additionally, interactive systems that enable new learning experiences may elicit a high volume of participant activity, which could be challenging to monitor. Recommendations are presented in Table 1.

Touchpoints and Recommendations
1. *Communicating clearly with text.*
☐ Evaluate study consent materials for the intended audience.
☐ Limit boilerplate language.
☐ Provide contextually relevant examples to define study specific terms.
2. *Providing for multiple learning styles.*
☐ Provide researchers access to tips and templates.
☐ For interactive consent processes, pay attention to version control.

Table 1. Recommendations based on the "Be concise" theme.

4.2 Promote transparency

Questions may naturally come to mind when learning about a study. In this section, we discuss *Introducing the research team* as a way to help people feel comfortable asking questions. The section also reviews ways to help researchers *field questions and offer responses.* A key consideration based on our analysis is how researchers and IRBs may use participant activity data during a consent process to infer whether participants understand the materials.

4.2.1 Touchpoint #3: Introducing the research team. Many participants expressed that they want to trust a research team before agreeing to participate. They want to hear how researchers respond to questions about their studies, "it's nice to see the people behind the study, be able to talk to somebody and get that human interaction" (P14). The principal investigator may not be the ideal contact for some questions, but people may not know who else to call, "I don't think people are going to call the program office, I think they'd be more likely to contact the research coordinator or somebody they may have emailed" (R31).

Prospective participants need to feel connected with researchers, "sometimes you have questions, but the idea of copy pasting an email address, and then composing an email, rather than having like a contact form with a quick question in it seems a bit more than you want to put into it" (P5). Privacy may be a concern. A prospective participant shared, "I tend to ask questions in the context of myself, that can be very personalized, and I wouldn't necessarily want that to be shared with everyone" (P13). Service providers suggested, "provide some other mechanism that are private for [prospective participants] to ask questions or communicate with you" (R37).

Helping people to ask questions also means committing to provide a response in a timely manner. From an IRB perspective, "if people are able to be consented without their questions answered, I think that would be problematic for the IRB members" (I25). Connecting prospective participants with the right members of the research team is critical, particularly for controversial topics. A service provider shared their experience helping prospective participants to filter through false information related to a study:

> "We followed up with a few people to try to understand what was going on and there seems to be a lot of spam out there, a lot of garbage and people don't necessarily trust that [the study materials were] coming from their health center. So one solution we talked about [was] creating a study website that people could look at and learn a little bit more about it and develop trust that this is a real thing not some scam where we're going to ask for their credit card information" (R37).

Some service providers were enthusiastic about the idea of appropriating existing online platforms to introduce people to the research team [34]. Responding to the idea *Building a social media presence* (section 3.4.1), a service provider shared, "this to me is more about customer relationship management, you're starting or establishing [a relationship] online" (R34). However, using social media may also invite unwanted attention, such as trolling, "I wonder if TikTok will just give this influx of too much, maybe like too many bad users" (P19) and "I don't want you guys [researchers] to get skewered on social media" (P9). How might we help people interested in a study to feel comfortable raising questions, while mitigating the risk of a study team getting trolled?

4.2.2 Touchpoint #4: Fielding questions and offering responses. Information technologies can help to elicit questions, but coordinating a response is not trivial. For example, referring to the idea *Hosting virtual learning sessions* (section 3.4.7), participants felt that "[chat bots] are pretty much useless" (P9) and "let me press zero as many times as I need to get to speak to somebody" (P19). In particular, "I really get annoyed when they just don't answer my question" (P13). If a question is less common or includes less familiar terms, then responses from a chat bot may be less useful, "like you asked one question and the answer is for a totally different question because it has one word [that's common]" (P40). When these frustrations set in, prospective participants want ways to reach a researcher.

Another way to elicit questions during a consent process is to include a quiz. Prospective participants said that embedded quizzes should provide an opportunity for participants to confirm understanding and correct misunderstanding, "for the folks who don't want to retest [...] just showing them *this* is the correct answer and then letting people proceed can be a way to meet

people in the middle" (P13). Formatting can highlight correct responses, such as using color to "turn the correct answer green [...] and at the bottom add a little bit of an explanation" (P13).

Service providers expressed some trepidation about how to handle incorrect quiz responses. If people "take the quiz and didn't do well, what would happen next?" (R34). Should people who score less than 100% be allowed to consent to participate? A low score may be due to ambiguous wording in a question, as a prospective participant shared that they would challenge any incorrect response. "Not to sound arrogant, but I have taken so many of these quizzes [...] and actually the questions themselves are not worded well enough, and so [if I got a question wrong] I'll be like, *no I didn't*, and I will show you how this question is not clear, because blah blah [...]" (P9).

Despite the difficulties, service providers expressed interest in the system logged activity data associated with question and answer systems. A service provider said, "so to me it's better data than what we have with just consent forms that you send out, if you're not observing [people] actually reading it and being right there and having a study coordinator there to answer questions [...] from the standpoint of having the data, it's a lot more appealing and attractive" (R31). Many service providers echoed this, but cautioned against adding burden to participants.

> "I could see the IRB wanting us to justify that, because any hoops we're asking people to jump through is a potential burden, so if they have to go through and answer a quiz, it would need to be very clear [and be] something you can elect to do to kind of check your knowledge before you sign off [on the consent form]" (R33).

4.2.3 Summary. Introducing prospective participants to the research team can help them to feel comfortable asking questions. Fielding questions and offering responses can be challenging for service providers, but the data associated with these processes could be useful for assessing participant understanding about a study. Our analysis identified recommendations to alleviate these challenges, which are synthesized in Table 2.

Touchpoints and Recommendations
3. *Introducing the research team.*
☐ Provide contact and biographies for the research team.
☐ Pay attention to privacy concerns when sharing questions.
☐ Ensure all questions are answered before participants consent.
☐ Respond quickly and publicly to false information.
4. *Fielding questions and offering responses.*
☐ Include ways for prospective participants to connect with a human.
☐ Provide people with lightweight ways to raise questions.
☐ Carefully consider whether quizzing adds value to the user experience.

Table 2. Recommendations based on the "Promote transparency" theme.

4.3 Value time and effort

Time is precious for prospective participants and service providers, alike. The following sections discuss several tensions related to how people invest their time in a consent process. Futuristic consent processes can help people to weigh study risks, but participants want these to be optional. Futuristic consent processes can also help people to navigate study details, such as with subsections, hyperlinks, and other structural elements; however, participants are concerned that they may get lost down rabbit holes, by *clicking* into details.

4.3.1 Touchpoint #5: Helping people to weigh risks. Our analysis found that participants are willing to devote more effort to understand studies that are high risk, than low risk studies, as long as the study risk is not too high. Additionally, if a study involves low levels of risk, but the consent process requires a high level of effort, then people are likely to get annoyed and abandon the study opportunity. In response to the idea *Hosting virtual learning sessions* (section 3.4.7), a prospective participant explained how the level of risk and interest in the study would affect their motivation to learn the consent materials:

> "[I]f it were like a multi month huge study where it would require a lot of my time and effort and [...] maybe they'll require DNA samples [...] like something really massive then I might actually have a number of questions that I would actually want to log on to a Virtual Town Hall and actually discuss with someone, because I might be on the fence. For your average study, I don't know who would log into this [virtual learning session]" (P9).

Weighing study risks may be hard, if the risks are less familiar. A prospective participant suggested that futuristic consent processes could provide, "maybe tools or information that helps them apply that [risky situation] to themselves, and how much risk [they are willing to consider], because I know that consent forms include the assumption of risk, but that doesn't always apply to the way the subject sees the risk" (P5). In this way, a consent process could become a means for people to explore their tolerance for some specific risks. For example, a prospective participant shared a recent experience completing several mandatory "bullet point questions" to review the consent material. The questions focused on specific study expectations, such as "is this data going to be shared with other researchers, yes or no" and "do you need to answer every question on the questionnaire, yes or no" (P7). The participant felt that, "it made me kind of like the study more, because it seemed like they cared that I understood what the privacy entailed. [A]nd because it was mandatory, everyone was getting these questions" (P7).

Service providers could prioritize helping people to quickly assess their tolerance for study risks. If "[embedded quizzes are] optional, the burden is on the research team, and the IRB to create, review, [and] approve, and then if they're under utilized, you know that's a risk of the research team" (I38). Some participants may also be resistant to participating, as many participants expressed strong distaste for mandatory activities in a consent process, "I wouldn't appreciate it, if they were mandatory. Optional, then I might check them out, but I would begrudgingly do it if it was mandatory" (P12). Designs that help prospective participants to quickly assess their understanding could be valuable, so long as they do not add burden.

4.3.2 Touchpoint #6: Navigating consent resources. Navigating a standard consent form typically means reading from top to bottom, perhaps skimming over some sections, while carefully rereading others. Digital technologies enable a wide variety of ways to navigate consent materials online, from menus of hyperlinked content, to hover over examples, and keyword search tools. Prospective participants and service providers generated several recommendations about how to help people navigate online experiences of a consent process.

Provide overviews of the material. Visual aides can help prospective participants to gain a high level view of the content, "[i]f they can see what they actually have to do, or what happened to them in a more visual way that usually helps with comprehension" (I25). An overview of the study may also help people to find their way into different parts of the material that interest them, as a prospective participant shared, "when people are choosing to learn about a specific thing, the way they process is different, rather than quickly scrolling through a whole piece" (P5).

Provide people with estimates of how much time a consent process may take. "Sometimes, when you read newspaper articles at the top of it will say something like one minute to read, five minutes

to read, something like that could be a thing" (P5). People may want to take additional time to review some sections. Online systems can use logged user data to help people to step away without losing their place in the consent materials. Prospective participants suggested that this capability would encourage people to consume the materials at their own pace. This may be harder with some online platforms, "I think another issue with social media is that it could be harder for people to be able to go back and refer to the informed consent" (R24).

Use hyperlinks sparingly. Providing references can promote a sense of trust, "adding definitions and context [...] means that they want you to understand, and if you want someone to understand something you're not trying to hide something from them" (P5). Too many hyperlinks can lead to confusion, "if it was a new pop up every time it would just get very overwhelming. [It would be better to] sort of get that information without having to feel like, *now I have all these tabs open*" (P7). Participants want everything on one page, "instead of hyperlinking to a different page, because that's where I could see it getting confusing, [...] if you click on it, and just brings you down to a glossary at the bottom of the page, *Okay, this is what [insert term] is*" (P13).

However, if people skip a hyperlink they may miss vital information. In response to the idea *Adding definitions in context* (section 3.4.4), a service provider said, "I like the idea of this being a shorter document, because some of the definitions are hidden behind links or pop ups, but I think there is that concern about what's being put forward is important, and not left behind a pop up or link" (I25). Another service provider described the content behind hyperlinks as a "second layer" that prospective participants would need to read through, but also raised the concern, "would they understand it?" (R24).

From an IRB perspective, is it necessary for people to click into every hyperlink in order to be considered informed? Service providers raised two scenarios to discuss this point: First, online platforms could monitor user engagement with the system to automatically track whether, "people access every piece of the informed consent, if it's not all together in one place" (R30). Second, online platforms could obligate people to access every piece of the informed consent materials, "so you have to click all them before you can click accept" (R22). How might service providers leverage system logged user activity data to promote understanding among prospective participants?

4.3.3 Summary. Time is an important consideration when creating consent communications. Our analysis found that people value additional learning resources when they perceive study risks to be high enough to warrant a careful review of the consent materials. However, if the risks are low, then requiring participants to engage with these resources can create a barrier to recruitment. Specific recommendations are summarized in Table 3.

Touchpoints and Recommendations
5. *Helping people to weigh risks.*
☐ Evaluate prospective participant perceptions of risk in a study.
☐ Provide ways for people to assess their tolerance for study risks.
6. *Navigating consent resources.*
☐ Provide an overview of the material to help people find information.
☐ Provide estimates of how long a consent process will take.
☐ Use structural elements to help orient people.
☐ Use hyperlinks sparingly.
☐ Evaluate what content should be linked versus presented *on-load.*

Table 3. Recommendations based on the "Value time and effort" theme.

4.4 Cultivate trust

Prospective participants may experience a range of emotions associated with a study. This section presents our analysis of how consent processes may affect feelings of trust in research. For example, opportunities to engage with researchers can promote trust, whereas user experiences that elicit feelings of confusion may diminish trust.

4.4.1 Touchpoint #7: Averting feelings of guilt and nervousness. In response to questions about what motivates people to review consent materials, participants conveyed a combination of guilt and concern. "I definitely don't want to be one of those people that just signs something blindly" (P19) and "I think for my own comfort I would at least click and expand each topic, if I couldn't I wouldn't just *sign here*, that would make me too nervous" (P19). Service providers expressed concern about the nervousness that prospective participants can feel during the process. "People are nervous doing these things, even if they're not necessarily going in for surgery, I think there's a certain amount of feeling on the spot, to read it" (R34).

Prospective participants shared that they like how some futuristic consent processes may involve steps to mitigate potential risks in a research study. In response to the idea *Estimating time commitment and risk* (section 3.4.5), "I think it's very thoughtful. On the few studies I've been a part of I felt a lot of stress about not submitting a survey in time or just dropping the ball [...] so the thought of an App or automated reminders, that would be just helpful for me, less stressful" (P15). Another shared, "I want to know all the information, as much as possible, so like you mentioned the Google calendar synchronize, I live and die by my Google calendar, so I would love that" (P19). Some appreciate the opportunity to reflect on their use of technology.

> "I do like the idea of being able to categorize things based on like is this listening to me, does it know my location, that sort of thing, being able to cross cut the data in that way, I think [that would] be very fun, and very enlightening" (P9).

Providing participants with ways to view potential risks in the context of their daily schedule, current privacy settings, and other considerations could help to alleviate some nervousness around study expectations. However, service providers should carefully weigh how the choice of technologies used to facilitate such an experience may play into participant feelings around a study.

Accessibility issues related to a technology can also limit access to research. For example, "if you're targeting like low tech literacy participants or older participants, then you're not going to get anyone [with these designs]" (R22). It can be challenging for researchers to exclude certain demographic groups, "approaching people through Facebook groups, I also think that there would be concern about who the target audience would be, and making sure that they were targeting the right individual, and not children, for example" (I25). Many felt that there need to be low tech paper-based options, "I'd only be okay with it [digital consent], if you still have the option for all this information to be given to participants who don't have Internet or a computer, because if it's only a website that really excludes a lot of people" (P13). Service providers need tools to evaluate how their choices about study technology may affect feelings of trust and participant access.

4.4.2 Touchpoint #8: Maintaining reviewability. Prospective participants value knowing how to find the details of a study, whether in their email, a study specific website (Idea #2, section 3.4.2), or through a standalone application (Idea #5, section 3.4.5). Providing participants with a copy of these details is standard practice, "a lot of IRBs would like people to have either a physical or electronic copy" (R24). However, people only need this information when they *need it*:

> "I'll get a call, and you know they'll be like, *hey you signed up for this study you know, etc, awhile back* and they don't specify what specifically, and I'm like trying to decipher

what they're talking about, what dates, I'm googling you know specifics [...] to see if it matches up with an email, you know" (P19).

Participants may want to consult the consent materials, if they have a question after the study concludes. A prospective participant shared how they would use the standalone study App described in *Estimating time commitment and risk* (section 3.4.5), "you could also see like past studies you've participated in you know, and I mean if, in case you have more questions [...] people like [being able to say] *oh yeah I did this*," when reviewing the studies they have participated in over time (P5). Providing this access later demonstrates respect to participants. If obtaining *broad consent* [36] becomes a more common way to generate large collections of personally identifiable and sensitive data for machine learning and artificial intelligence health research, then study participants will likely want ways to review the variety of secondary analyses that benefit from the use of their personal data over time.

Prospective participants also appreciate knowing the results of research. "So if I were interested in getting any information about, like outcomes, later on down the line [the website would provide] a feedback loop where you can go back and look at the results of the study" (P11). Viewing the results of a study can offer participants a benchmark on their personal progress towards a health goal, for example. "If I could see my results on my progress [...] I just think that that would like both build trust [...], but also like further engagement, because I could actually see what I'm contributing to" (P41). In the process of returning results, study participants may also help the research team to understand trends and outliers by sharing personal experiences of the data [48].

Service providers raised concerns about returning study data to participants. Speaking about the idea *Presenting in multiple formats* (section 3.4.2), a service provider shared: "I keep getting stuck on [the system feature] *monitoring your own progress during a study*. Certainly, you can monitor your adherence to the tasks, but you wouldn't want people to necessarily be privy to their own performance data, because it could bias them" (R21). While providing participants feedback during a study can boost retention and demonstrates respect, care should be taken to make sure that doing so does not compromise the research objectives. Additionally, sharing some types of study data may not be in the participants best interest, for example, participants in a digital mental health study may not respond well to information about trends in their emotional state. Researchers should exercise caution when considering what types of data to return, at what levels of granularity, and whether to a study participant or to other stakeholders in their well being (e.g., family, friends, clinicians, emergency support staff) [48].

4.4.3 Summary. Cultivating trust in research involves paying attention to participant feelings, technology choices, and providing ways for participants to reconnect with study details. Service providers raised several considerations when making these decisions. Specific recommendations are summarized in Table 4.

Touchpoints and Recommendations
7. *Averting feelings of guilt and nervousness.*
☐ Help people to evaluate time commitments, e.g., calendar syncing.
☐ Include information about how data is collected and used.
☐ Choose technologies that are broadly accessible.
8. *Maintaining reviewability.*
☐ Use key terms to help participants search for study materials.
☐ To the extent possible, return results to participants.

Table 4. Recommendations based on the "Cultivate trust" theme.

4.5 Navigate platform specific risks

Standard consent practices collect minimal data by comparison to the futuristic consent processes central to this study (section 3.4). The US Common Rule subsection "Documentation of informed consent" (§46.117), stipulates that unless waived by the IRB: "informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form." Our analysis identified concerns about managing data that could be collected through futuristic consent processes.

4.5.1 Touchpoint #9: Managing data and privacy. Typically, service providers have limited information about whether people have actually understood the consent materials. Many service providers remarked that the futuristic consent processes would provide an opportunity to learn how people review these documents. Currently, "we don't know when we're sending off these written forms, if participants are spending time to read each section, how long they're spending on each section, having that information could be potentially informative" (R32). Such insights could help service providers to tailor their communications to prospective participant needs.

Simply collecting this data can create a risk for people. At a fundamental level, if participants answer quiz questions in a consent process, that reflects data being collected, " [...] then they almost need to consent to their responses being used to assess if they're able to participate in the study, and so I think it creates a lot of levels [for IRBs] to consider" (R32). Data collected during a consent process may also include sensitive information.

> "I've had a patient tell me, *you know I smoke, please don't tell my oncologist that I'm smoking*, and I'm like why would you think I would tell my colleague that you're a smoker, but there's just this idea that data is just kind of shared" (R27)

For research involving mental well-being, there may be additional considerations for data privacy, "there's a lot of concern [among university students] about, you know *is my doctor or college going to see this stuff too* [...] I think people want to make sure that there's kind of firewalls in between things" (R27). Service providers recommended working through these details with the IRB by focusing on, "how it's a value add for participants, in terms of informed consent, and that it doesn't include additional risks to privacy and confidentiality" (I25).

Third-party platforms used to facilitate a digital consent may also collect and use prospective participant data. For example, if social media platforms are used to facilitate some aspect of a consent process, showing interest in a study may pose a risk for the user, "you know substance use [studies], you wouldn't necessarily want to put your name out there asking questions about it" (R39). Service providers raised several concerns, "how are these tech companies using our data and improving their algorithms" (R21) and "my institutions IRB would be having a million questions about what data is being captured about users who are following links over [TikTok] to any kind of consent thing" (R23). When communicating the use of a third-party platform to an IRB, service providers should remember, "not all IRB members are comfortable with technology solutions and that can be a burden in and of itself" (R33).

Service providers may also struggle to evaluate the risks associated with some novel technologies, due to challenges accessing data. For example, "I can give them [the IRB] links to the videos, I can give them a link to frequently asked questions, but I don't know about a chat bot. There's no way to predict what would come in and what would go out from it, so it's kind of a black hole to the IRB" (R24). This raises open questions, such as how might IRB members access and review data used to train interactive systems, like a chat bot, for use in consent processes?

4.5.2 Touchpoint #10: Managing responses at scale. How might sociotechnical systems help researchers to manage prospective participant communication in large studies? In studies with a moderate number of participants, "they can always pick up the phone and call or shoot us an email [...] that process seems to be working" (R33). Digital studies can feel less personal, "we never saw our research participants face to face, and giving them a 15 page consent document was just not ideal, for us, or them" (R39).

Online discussion systems may help to facilitate researcher-to-participant communication. "One thing that I can think of is like if there's a place where people can write in comments, anything that collects anything from the patients, would have to be moderated" (R34). While existing content moderation research has focused on how to remove contributions that violate community norms (e.g., profanity, trolling, spreading misinformation) [42], moderators of a consent process may inadvertently remove comments that probe too much at study details. As an example shared by a service provider, "if we have an ongoing study and we have study participants who are asking questions, and maybe this isn't the right place to do it, but they will do it, if they are going to ask questions about the study itself in this system [...] you could have a privacy breach that I can imagine an IRB being concerned about" (R37).

Futuristic processes could generate content that is tricky to moderate, like social annotations. For example, in order to embed a quiz, "the burden is on the research team and the IRB to create, review, and approve [questions and participant responses]" (I38). Moderating these contributions will require training, "[the] amount of preparation, legal or otherwise, that in every response, and on the zoom calls, to make sure you are able to answer everyone's questions fully, I think that takes a lot of work [...] maybe lawyers will be involved" (R26). Addressing these concerns in a content moderation protocol could be challenging.

Futuristic consent processes may also generate a lot of noise, "I love immersing myself [...] but, when you wake up in the morning and your phone has 1000 notifications [...] it can be a bit unnerving" (P19). Participants recommended service providers pay attention to timing, pace, and message volume. When we asked what communication methods we may have missed, a service provider said, "the one that jumped out is the ability to text with a study team [...] because [SMS] texting is often underutilized and one of the best ways to communicate with participants" (R31).

4.5.3 Summary. Futuristic consent processes have the potential to collect granular levels of data, which may contribute to research about science communication, but raise concerns about data privacy. Our analysis highlights open questions for system design and policy: (1) How might we protect the rights of people who choose not to participate? (2) What technologies might service providers use to maintain clear, consistent, and compliant communication with large audiences of prospective participants? Specific recommendations are summarized in Table 5.

Touchpoints and Recommendations
9. *Managing data and privacy.*
☐ Be mindful of how logged activity is used to make inferences.
☐ Carefully consider participant expectations about their data privacy.
☐ Disclose potential risks introduced by third-party technologies.
10. *Managing responses at scale.*
☐ Use a content moderation protocol for your consent communication.
☐ Develop tools to help moderate complex contribution types.
☐ "Low-tech" solutions, like SMS/texting, can be sufficient.

Table 5. Recommendations based on the "Navigate platform specific risks" theme.

5 DISCUSSION

The use of online systems to facilitate informed consent in digital health research is becoming standard practice (e.g., *mPower* [7, 16]). Digital consent processes have the potential to communicate opportunities to participate in research with large audiences, yet service providers foresee various barriers to facilitating these processes. To identify the opportunities, barriers, and potential unintended consequences associated with futuristic consent processes (Section 3.4), our research applied a Service Design lens [69, 73]. This approach involved rapidly exploring a series of possible futures [78] with prospective participants in research who view consent processes from the *frontstage*, as well as researchers and IRB members who help to design, review, and facilitate consent processes from the *backstage*.

The Findings present five principles to improve informed consent processes in digital health: i.e., be concise, promote transparency, value time and effort, cultivate trust, and navigate platform specific risks. As outlined in the sections that follow, our analysis points toward several practical steps to prepare for futuristic consent processes in digital health. These steps include:

- Integrate recommended best practices into the process of designing a consent communication, whether as tips alongside existing IRB templates or entirely new workflows for launching digital health studies through recruitment platforms, like Research Match.
- Develop guidelines and protocols for moderating content generated during digital health consent processes, by working with professional societies and other stakeholders.
- Create tools and training programs to help IRB members and community representatives to evaluate digital health study materials prior to recruitment, as futuristic consent processes may yield complex forms of data.

5.1 Improve the process of designing consent communications

Our analysis identified recommendations for consent communication, which could be integrated into IRB templates and online recruitment platforms, like Research Match and Prolific. For example, the recommendations could be provided as a list of tips for researchers to consider before submitting consent materials to the IRB, such as "*Use examples of how your research team will respond to specific risks, such as a breach of* ***confidentiality****, rather than simply defining these terms*," to promote transparency. Online participant recruitment platforms might present these tips throughout the process of creating a study to prompt thinking about how to promote trust, understanding, and other valuable outcomes for prospective participants.

As researchers may not have the skills to create some futuristic consent processes, recruitment platforms could make these digital components available through a library of interactive templates. For example, online recruitment platforms could use a drag-and-drop approach to create a consent process from a set of templates, including FAQ lists, quizzes, and structural elements that help prospective participants to review materials at their own pace. Crowdsourcing researchers have experimented with similar ways of creating workflows with micro-task template libraries (e.g., *Foundry* [58, 71]), which can dynamically adjust based on user experience (e.g., *Fair Work* [75]) and elicit feedback to address points of confusion (e.g., *Sprout* [8]). As researchers drag-and-drop templates into their consent process workflow, the platform could present relevant tips. For example, dragging a quiz template into a consent process might trigger:

> **Reminder**: "*Prospective participants prefer optional quizzes that ask about important study risks in an objective way and provide a clear response with a reference to specific sections of the consent materials for them to review.*"

Template "reminders" could serve as short lessons in demonstrating respect for study participants. Providing such educational scaffolding [63] through the process of launching a study on an online

recruitment platform may encourage service providers to adopt better communication practices, in general. As another example, prospective participants shared that they want to trust a research team, by hearing how researchers respond to questions about their study. To design for this desire, some consent process templates could involve audio/video recording a canned interview with the researcher, such as to explain a data flow diagram of the study system [35]. The short audio/video presentations could be catalogued and shared with people through the recruitment platform. The act of recording the interviews may also create an opportunity for researchers to reflect on how they communicate about their work. While not all studies use online participant recruitment platforms, enough do that enhancing the consent communication design process at Research Match, for example, could meaningfully improve research communication.

Template libraries could also lead to rapid advancements in the practice of digital health research. A consent process template library could be used as a research platform for online experiments about how digital consent process interventions affect various desirable outcomes in the prospective participant experience of a study, such as understanding, feelings of trust in research, as well as perceptions of burden in the consent process. Online recruitment platforms could lead this research, but there could be some tricky policy considerations, as prospective participants may need to consent to participate twice: first, in research about a consent process intervention, and second for the research described by the consent communication. Despite these difficulties, such infrastructure for studying informed consent in online and large scale studies could help to continuously advance the ethical and responsible conduct of digital health research.

5.2 Create content moderation protocols to scale up study participation

Digital consent processes may include new types of user generated content. Enabling people to share questions, annotate consent materials, and review similar contributions made by other people during a consent process, may raise new barriers for service providers. For example, providing people with an opportunity to ask questions about a study is an important component of informed consent, yet many prospective participants fail to ask critical questions before they agree to participate [74]. Digital consent processes could help to elicit questions, such as by including an FAQ list or quiz, but moderating the large scale of content generated by these systems could be a burden for researchers. Another concern for IRB members is whether and how enabling people to review contributions made by others could result in prospective participants receiving different "versions" of the consent materials. To navigate these challenges associated with user generated content, service providers need guidance for content moderation.

Not every study will generate the level of interest necessary to warrant content moderation support for a consent process, but research about behavior within organizations and social systems may [61, 77], such as the infamous Facebook emotional contagion experiment that involved nearly 700,000 users [22]. Without careful content moderation and guidelines, prospective participants could inadvertently share personal information when using a consent process to create, review, and share questions. To address this concern, content moderation procedures might involve clustering questions by topic and then translating each cluster to remove personalized content, so researchers can share an anonymized general response. Crowdsourcing systems research has navigated similar concerns about data privacy in micro-task management (e.g., *EmailValet* [31]).

Depending on the nature of the topic area, content moderators might consult with IRB members, lawyers, as well as prospective participants to confirm how each question and response are presented. This type of inter-organizational coordination may be similar to how content moderators at news outlets work with journalists, data science teams, and regular contributors to fact-check the online discussion surrounding a breaking story [42]. Through the act of crafting responses to prospective participant questions, content moderators could also watch for telltale signs of misinformation

about a study, ranging from broken links to misquoted statements (e.g., [66–68]). As digital health technologies enable research that is truly large in scale, professional societies might begin developing guidelines for moderating content yielded by research practices, such as informed consent processes, when returning results to participants, and in other science communication.

5.3 Consider the risks associated with data collection during a consent process

Data collected by futuristic consent processes could help service providers to better understand how prospective participants learn about a study. For example, logged activity data collected through a futuristic consent process can help researchers to recognize potentially tricky sections based on the amount of time prospective participants spend (or do not spend) engaging with parts of the consent materials. The opportunity for researchers to learn about how people review consent materials digitally far exceeds the status quo, but collecting this data raises questions about how it might be used in practice.

(1) If a prospective participant chooses to skip over or skim sections, stop watching a video, or incorrectly responds to some quiz items, have they reviewed enough of the materials to consent to participate?
(2) If parts of a digital consent process access or share data with a third-party platform, like TikTok, what instructions do prospective participants need in order to protect their privacy?
(3) If people choose not to participate in research should any personal information collected about them by the system be removed/deleted, if not explicitly consented to use for the purpose of understanding why some people opt out of study enrollment?
(4) What resources might service providers use to maintain clear, consistent, and compliant communications with a potentially large audience of prospective participants?
(5) If consent materials are updated regularly, how might service providers manage version control, specifically which version each participant was presented, and when?
(6) How might service providers use informed consent processes to surface emergent risks associated with novel technologies in digital health research, such as machine learning and artificial intelligence?
(7) How might ethics review boards review data about a consent process to monitor and recommend ways to promote collaborative dialogue among researchers and participants?

Service providers may need training and data analysis tools to evaluate these issues. Involving community leaders and interest groups in the conversation about digital health research can be valuable as well, whether the research is conducted with in-person groups [39, 62] or online communities [10, 44]. These stakeholders may also value access to similar training and analysis tools to help them join in the planning conversations around a digital health study. As a possible framework for facilitating this collaborative work, Bernstein et al. [4] provides an example in the Ethics and Society Review board (ESR) of how to surface possible unintended consequences associated with novel technologies. The ESR might serve as a model for how research teams can facilitate conversations about the design of consent processes with community stakeholders and experts from various disciplines.

The steps outlined here will require more from service providers. So many of the processes in research participant protections derive from regulatory requirements, which can create a tension between designing informed consent processes that respond to the frontstage desires of prospective participants, backstage needs of service providers, and other interested parties, such as government regulators, funding agencies, and community-based organizations [32]. The ideal infrastructure for research participant protection needs to provide space for people to perform, feel motivated, find joy, and recover from intense periods of performance; sociotechincal systems can help to do this

[65, 73]. Our analysis suggests that service providers may experience immense burnout if some futuristic consent processes become normalized in research. While these designs may cultivate trust with prospective participants, they could not be facilitated without the thoughtful persistence of research service providers.

6 LIMITATIONS

The study presents formative research to explore potential opportunities, barriers, and unintended consequences associated with futuristic digital consent processes. Our analysis raised considerations toward the design of digital systems for conveying consent information. Future research should prototype these processes with a broad range of stakeholders involved in the conduct of research and human-subject protection in research. While speed-dating [78] was useful for our exploration into the digital consent process design space, a lo-fidelity cognitive walkthrough [59, 64] of possible interactions at each touchpoint would help to develop service plans that can be translated into hi-fidelity system prototypes [69].

A limitation of the research is that our recruitment procedures were limited to prospective participants, researchers, and IRB members. These are key stakeholders in the design of consent communication, but not the only voices. In practice, researchers only create consent materials occasionally. This task is often offloaded to program managers and graduate students to draft and submit. For this reason, standard IRB templates are often viewed as an instructional tool to help novices develop foundational skills in science communication. *This is the problem.* By presenting a variety of futuristic consent processes our hope is that readers will look beyond the standard template for inspiration about how to demonstrate the ethical principle "respect for persons" [2, 26] in digital health and CSCW research. Future studies involving novice researchers would help to identify learning gaps in the consent communication design process.

Another limitation is that our futuristic consent processes require access to broadband and computing systems (e.g., desktop computers, mobile phones, smart speakers). In multiple workshops participants noted that facilitating informed consent digitally could systematically limit participation in a study. Additionally, participants shared that some platforms, such as TikTok, may invite bad actors intent on trolling the research team or undermining their study. Future research should investigate ways to translate recommended practices based on our analysis into formats that can be communicated in-person, through pamphlets, and physical artifacts that can be mailed to prospective participants in areas with limited access to digital services.

Finally, our research centered on a digital health study context. Informed consent processes for research in other disciplines may require other considerations. For example, if there are only a few eligible participants for a field of research, then it may be important for consent processes to reference studies that each person has participated in previously, in order to elevate specific topics to carefully review. If a study involves sensitive information, then consent processes might include steps to ensure that the information will not be disclosed outside of the study. Recording information about people can also feel invasive, particularly for historically marginalized communities [17]. The extent to which researchers can involve community-based organizations representing prospective participant interests in the design of consent processes and management of their own personal data collected by the process, may help to cultivate trust in the research.

7 CONCLUSION

Informed consent is the cornerstone of human-subject research, yet consent forms are rarely designed for people. While research conducted within a physical lab or locale typically involves a member of the research team to help prospective participants interpret the often long, dense, and legal language in a consent form, such personal support is not always available or appropriate for

digital health research. Instead, digital consent processes tend to involve prospective participants interacting with a website or through a mobile phone to review consent materials. At a fundamental level, this study challenges that standard by applying a human-centered approach to explore futuristic informed consent processes that were explicitly designed to reflect what information prospective participants want to know about a study and how they want to receive this information, such as in short videos, interactive quizzes, or virtual "Town Hall" meetings. To consider possible design constraints associated with the futuristic consent processes, the study invited prospective participants, researchers, as well as IRB members to speed-date with the ideas [78]. Our analysis of the design speed-dating identified ten "touchpoints" [69] where prospective participants come in contact with researchers and IRB members, which we frame as five principles to improve the design of digital informed consent processes: be concise, promote transparency, value time and effort, cultivate trust, and navigate platform specific risks. Our results offer practical steps for futuristic consent processes in digital health and CSCW research.

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