Original Research Article

Considerations for the Design of Informed Consent in Digital Health Research: Participant Perspectives

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Brian J. McInnis[1], Ramona Pindus[1], Daniah Kareem[1], and Camille Nebeker[1]

Abstract

The research team, prospective participants, and written materials all influence the success of the informed consent process. As digital health research becomes more prevalent, new challenges for successful informed consent are introduced. This exploratory research utilized a human centered design process in which 19 people were enrolled to participate in one of four online focus-groups. Participants discussed their experiences with informed consent, preferences for receiving study information and ideas about alternative consent approaches. Data were analyzed using qualitative methods. Six major themes and sixteen sub-themes were identified that included study information that prospective participants would like to receive, preferences for accessing information and a desire to connect with research team members. Specific to digital health, participants expressed a need to understand how the technologies worked and how the volume of granular personal information would be collected, stored, and shared.

Keywords

digital health, informed consent, participant perspectives, research ethics, human centered design, research ethics committee/IRB review

Introduction

Health research, including clinical trials, is critical to the development of pharmaceuticals and for informing health promotion and disease detection and treatment strategies (National Academies of Sciences, Engineering and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Forum on Drug Discovery, Development and Translation, 2019). For those who enroll as participants, the informed consent process is considered an important gateway to ethical health research. The purpose of the informed consent process in health research is to convey study information to a prospective research participant. In the United States, the federal regulations require that informed consent be obtained when enrolling adults in health research (Protections (OHRP), 2017). The regulations speak to what study information needs to be communicated during the informed consent process but not to how the communication is designed and implemented. Ethical guidelines suggest that the consent conversation occur in a setting that supports an individual's ability to review the study information, ask questions and then, make a decision about whether to volunteer. Researchers begin the consent design process by synthesizing study details, such as the research purpose and procedures that the individual will complete as a participant. To initiate the consent communication, researchers typically follow a consent form template that is provided by the local Institutional Review Board (IRB) (Klitzman, 2013). The IRB provided consent templates serve as a guide to develop a written consent document that is aligned with federal regulations; however, many researchers have recognized the need to improve how study information is communicated to prospective study participants (Bloss et al., 2016; Munteanu et al., 2015).

Previous research has explored ways for researchers to improve the design of informed consent processes, in general. Recommendations include paying attention to language (Rudnicka et al., 2019), incorporating visual content (Reinhardt et al., 2021) and interactive features (Balestra et al., 2016). Moreover, recommendations to promote specific values in an informed consent process include gauging understanding (Breese et al., 2007; de Oliveira et al., 2017; Quinn et al., 2012), reading time (McNutt et al., 2008; Reinhardt et al., 2021), and trust (Reinhardt

[1]Herbert Wertheim School of Public Health and Human Longevity Science, University of California San Diego, La Jolla, CA, USA

Corresponding Author:
Camille Nebeker, Herbert Wertheim School of Public Health and Human Longevity Science, University of California San Diego (USA), 9500 Gilman Drive, MC 0811, La Jolla, CA 92093-0811, USA.
Email: nebeker@ucsd.edu

et al., 2021). Improving the design of the informed consent communication can be particularly impactful toward involving vulnerable or at-risk populations in research (Anderson & Iltis, 2008; Munteanu et al., 2015; Quinn et al., 2012). When people feel as though they are not well informed about a study, then they are less likely to participate (Breese et al., 2007; Willis, 2006). Even if they still have unanswered questions about a study some people may still choose to participate but possibly at greater risk than they realize (Walkup & Bock, 2009). Both outcomes are detrimental to science.

Creating standards for the design and evaluation of digital consent processes is increasingly important, particularly in the health sciences. Over the past decade, there has been rapid expansion in the use of digital technologies (i.e., wearable sensors, mobile applications, social media platforms) in the collection of personal health data and/or delivery of personal health and wellbeing interventions (Coravos et al., 2019). This field of research is now widely recognized as "Digital Health" research. Data collected through digital health research may include passive collection of information about behavioral health (e.g., physical activity, medication adherence, sleep), physiological markers (e.g., heart rate and heart rate variability) and environmental factors (e.g., air quality). The tools may also involve active data collection instruments, such as ecological momentary assessment surveys that can be deployed on a digital device like a smartphone.

Digital health technologies are making it possible for people to enroll and participate in clinical research from the convenience of their home. As remote enrollment increases, it is likely that the informed consent process will become an interaction between prospective participants and a computing system. Moving from a face-to-face interaction with research staff to a self-paced review of study information on a tablet or website can raise concerns about accessibility. For example, the All of Us Research Program allows participants to enroll as contributors to a digital health data repository via their tablet or via the website (Doerr et al., 2019, 2021). Another example is the mPower study that involved self-consent to participate via a mobile app for monitoring early signs of Parkinson disease (Doerr et al., 2017). The ability to enroll participants in remote settings increases the possibilities of digital health research at scale. In these cases, the feasibility of a one-on-one consent conversation between a research coordinator and prospective participants is unrealistic. As digital health research involves more complex tools and methods to produce data (Dunseath et al., 2018), people need thoughtfully designed and rigorously evaluated processes for learning about the purpose, procedures, risks, and benefits associated with their participation in that research (Luger & Rodden, 2013).

This paper presents formative research designed to facilitate the development of consent processes that are human centered and respectful from the perspective of prospective participants in digital health research. The study involved recruiting people eligible to participate in a larger digital health parent study (referred to hereafter as "HealthyBaby") supported by the National Institutes of Health. In HealthyBaby, moms and babies will participate in a longitudinal, observational study in which some data will be collected using wearable sensor technologies. We invited people who would be eligible to contribute to the parent study, women of childbearing age, to attend an online focus-group. During the focus group, participants were asked about their experiences with informed consent, preferences for receiving study information, and ideas about alternative approaches. Members of the research team analyzed comments from the workshops through a qualitative affinity diagramming process (Holtzblatt & Beyer, 2017). Our analysis identified six major themes and sixteen sub-themes reflecting what information prospective participants would like to receive as well as how they prefer to receive it (see Table 1). We discuss how the themes can be used by researchers when creating informed consent processes that are human-centered.

Methods

The study was verified as exempt from IRB review under U.S. Section 45 CFR 46.104(d), category 2: "Research that only includes interactions involving educational tests,

Table 1. Thematic Categories and Number of Associated Statements.

Category	Statements
Research consent process	
Experiences	13
Personal opinions	110
Desired information	
Prior to consenting	66
During a study	14
After a study concludes	15
Ideas for improvement	
Participant ideas	96
Researcher statements	
Protocol instructions and qualifications	344
Participant questions about protocol	19
Total	677

Statements were hand-coded collaboratively by four members of the research team. Each statement reflects a complete thought within a speaking turn. The statement codes were based on when the statement occurred in the focus group protocol and whether the statement communicates an experience related to the informed consent processes, an opinion, desire for information, or idea for improvement. Statements about Experiences related to typical research consent processes, Desired information, and Ideas for improvement from the focus group transcripts were analyzed through an *affinity diagramming process* (Holtzblatt & Beyer, 2017) (30%, N = 204 statements). The team deliberation about themes took place over a 6-week period, which concluded when reaching consensus.

survey procedures, interview procedures, or observations of public behavior." Though exempt from the Common Rule, the study procedures involved a consent process as well as several steps to protect the identity of the research participants, which included password protecting any personally identifiable information, limiting data access to research team members, and assigning participants to randomly generated unique identifiers and removing any potentially personally identifiable statements from the transcript data.

Four focus groups were conducted in September 2021 via online video conferencing. The participants (N = 19) included women of childbearing age, as this was the population of interest in the parent grant of which this bioethics supplement award was linked. Participants were recruited through a variety of sources, such as 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.

The informed consent communication for our supplemental study was included in a survey sent to prospective participants via e-mail, which included a condensed description of the study and a link to an interest survey. The online survey included the full text of the consent information on the first page followed by a question asking prospective participants if they would like to join the study or decline to participate. Those declining were able to exit the survey. Those agreeing to participate were asked a series of questions about their prior research participation and preferences.

The focus group protocol involved the following: introducing the research team and objectives (5-min), describing a specific digital health technology (5-min), and then semi-structured discussion about what information participants would like to know before agreeing to participate in research involving the technology (25-min), followed by another semi-structured discussion about how that information might be presented (25-min). To prompt discussion, we chose to present digital health technologies used to monitor and motivate physical activity, as fitness monitors are used in digital health research studies. Each of the four focus group sessions involved 4–7 participants and took 60-min to complete. Participants received $50 for their participation.

Audio from each online focus group was machine transcribed. All participant names were replaced with unique identifiers by research team members who reviewed each transcript by hand. The transcripts were systematically parsed into 677 statements, where statements reflect a complete thought within a speaking turn. After removing researcher statements from the analysis, in total, 314 statements (46%) were made by participants. To explore what information people desire throughout an informed consent process as well as their ideas for improving the consent process, our team initially organized the statements into the following categories: personal opinions and experiences with consent processes, desired information prior to consent, during the study, after the study, as well as ideas for improvement (see Table 1)

Results

Demographics

Participants (N = 19) included women of childbearing age who were a mean age of 31.9 years. While participants were recruited through several sources (see Methods section), most of those volunteering were from Research Match and included women from nine states within the United States who identified as White (n = 7 or 36.8%), Asian (n = 6 or 31.5%), Black (n = 3 or 15.7%), Hispanic (n = 2 or 10.5%) and multi-racial (n = 1 or 5.2%).

Our analysis identified the following six themes: (Theme A) participants want to know about technology, (Theme B) participants want to learn about specific expectations for participation, (Theme C) participants want to understand data collection, protection, and sharing practices, (Theme D) participants want to confirm that they understand the consent material, (Theme E) participants want access to multiple and interactive ways of reviewing the consent materials, (Theme F) participants want ways to keep in touch with researchers (see Table 2). The six themes describe the type of relationship that prospective participants want to cultivate with researchers.

Rather than simply being handed a catch-all consent form, prospective participants want to explore how study technology may play into their lives. As digital health research can involve the collection of sensitive data and interventions that address personal health concerns, for prospective participants the informed consent process is an opportunity to cultivate the trusting relationship that they want with a research team. The sections that follow present each theme in depth, drawing illustrative examples from the focus group transcripts.

Theme A: Participants want to know about the technology. Digital health studies can involve collecting a substantial amount of personal data at a granular level, including location, social media posts, heart rate and other biological monitoring, emotional state, etc. "I want to know what additional information the app is tracking?" (P11) Participants were especially concerned about specific types of data, "I wouldn't want any kind of voice tracking, like picking up on any speaking, like a Siri kind of thing" (P16), and "whether or not my location is being tracked in any way" (P11), and "how it's [the data are] being stored" (P17).

As some digital health technologies are integrated with personal devices, participants expressed wanting to know what other types of data researchers may be collecting, "if you're accessing data from my phone via Fitbit, what can

Table 2. Clusters and Theme Descriptions.

Clusters and descriptions	Statements
Theme A: Participants want to know about technology	
1. What steps will be taken to protect my privacy?	11
2. How can I get the most from using the technology during the study?	15
Theme B: Participants want to know about the expectations for participation	
3. How will I be communicating with researchers, staff, and other participants, etc?	17
4. How much time and effort is going to be involved with the study?	5
Theme C: Participants want more information about data (e.g., collection, sharing)	
5. I would like updates about the study results and any publications after the study	21
6. What are the study data collection and sharing practices?	12
Theme D: Participants want to confirm their understanding about the study	
7. I want the consent information in advance, so I can take my time reviewing it	9
8. I want help confirming that I understand the consent materials	8
9. I want consent materials that use clear and concise language	12
10. I think that researchers should account for different learning styles	13
Theme E: Participants want access to multiple and interactive ways of reviewing the material	
11. I think that an online process could be designed to promote learning	24
12. I prefer short videos and interactive tutorials to reading forms online	8
Theme F: Participants need ways to keep in touch with researchers	
13. I want to meet and feel comfortable with the research team	10
14. I would like to know how my performance compares to other in the study	13
15. I would like to feel encouraged throughout the study	6
16. I want reminders about consent material and my rights as a participant	20
Total	204

Themes emerged from the analysis of phase 1 statements. Included in the analysis are statements about participant experiences related to typical research consent processes (N = 13), desired information (N = 95), and ideas for improvement (N = 96) from the focus group transcripts (N = 204 statements, 30% of all participants) (see Table 1). Following an affinity diagramming process (Holtzblatt & Beyer, 2017), global themes (A-F) include a max 4-6 area themes (1–16), which includes a max 4–6 issue labels (not presented), which include no more than 4–6 statements from the Phase 1 focus group transcripts. To promote empathy through the design process, each area theme was written as a question or desire from participants.

you see? What can you not see?" (2-4-1). Prospective participants want to have a sense of how the study technologies work, so that they understand how data about them is collected, whether they can review that data, and if they can potentially pause data collection during a study (Theme A). When participants asked about study expectations and procedures, many of their questions revolved around whether they could turn off study data collection. "What risks would be involved in wearing it, would I be allowed to take it off?" (3-2-1). Participants were particularly concerned about the granularity of data collection, "people have mentioned just kind of tracking, I'd be kind of wary about that as well, unless I had access to it, like how to turn it off or on" (2-11-2).

Some digital health studies involve novel technologies that are less familiar. A few participants in our study expressed that, while they personally may not need help understanding a technology, they know that others may. For example, "I know there aren't any risks in using a Fitbit, but I was just thinking about other people I know, maybe not myself personally, who would like to know what is involved in this Fitbit" (3-10-1). This finding exemplifies the type of digital literacy barriers that can leave a prospective study participant reluctant to share their concerns about a study, regardless of whether they choose to participate.

Theme B: Participants want to know about expectations for participation. Participation in a digital health study inherently requires time and effort. Before agreeing to participate, prospective participants want to evaluate whether study participation will fit into their day-to-day life. People want study expectations presented in a format that is easy for them to compare with their existing commitments. "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). In this example, a participant suggested that digital health researchers could provide people with a Google calendar that they can use to keep track of study requirements: e.g., lab visits, survey taking.

In addition to understanding time commitments, prospective participants want to explore the level and types of effort that may be expected. For example, when considering a study that would involve wearing a Fitbit smartwatch participants asked, "would you have to wear it when you were

sleeping, would you have to wear it when you're in the shower?" (3-67-1). In addition to wearing sensors, some digital health studies involve responding to surveys and communications from the study team, "for the notifications that there's a response required, is there a time limit for the response? I've done research before where you had a certain amount of time to respond and if you didn't, then didn't count [your participation]" (1-18-2). These observations highlight that demonstrating respect towards participants also means paying attention to how their time is valued through study participation.

By joining a study, participants may gain access to new resources. For example, in the study context used for our focus groups, participants would gain access to health coaching services to support their physical activity and weight loss goals. Prospective participants asked, "I think there's kind of two things that came to mind for me. The first one is like health coaching, you know, it's under notifications, but my question, is that purely from notifications? Or is that through telephone calls, like, is there an actual coach, is it from a program [smartwatch application]?" (1-14-1). Digital health researchers can help to address the concerns people have about their time and effort by providing schedules for the research, which can then be used to prompt participants to reflect on how their daily routines may align or not with study expectations.

Theme C: Participants want more information about data management (e.g., collection, storage and sharing). Several participants remarked that, after a study concludes they, as participants, rarely receive information about the findings, "[…] and when the study is over, I never hear about it again. So, I feel that I've been accustomed to that," (2-41-2). One participant expressed how disingenuous it can feel to be promised follow-up information, yet never actually receive a follow-up from the research team:

"I've never got the promises I've received from research studies. [Researchers say:] *Oh, we're going to give you the data we collect from time to time and show you what we got* […] I've never received any of that. So, it would be really nice to actually receive that for once" (2-50-2).

In response to these concerns, participants shared two types of information they would like to receive after a study concludes: (1) information about how their data are shared through the course of subsequent analyses, and (2) information about the research findings. People are concerned about how their data from a research study are shared, because of their concerns about privacy and security, "there's so much information that's coming out recently about like data breaches and you know information sharing, that we weren't aware of. I don't know that I trust the security and goodwill of some of these systems." (P11).

Participants want to keep informed about how their data are accessed after a study concludes. "I feel that if the information is going to be shared, would we receive a notification [about] who it is being shared to in the future, such as any kind of private companies or government companies?" (2-20-1). Other participants felt that, if their data would be shared, then it should only be shared at specific levels of observation, "I would want only [data at the] group to be shared, [and only] what was written down [in the consent, e.g.,] weight, heart rate. Any other things I would need to be notified in writing and consent too" (P16).

Participants also want to learn about the findings from a study. "I think when the study is over, like seeing some sort of you know, graph of like where did the group start and where do we all, like having that" (3-130-1) and "I'll read the journal article, or whatever paper you publish, when it's published, just send me an email about it" (2-41-4). The participants might even be involved in a final review of the research, for example, "maybe with the email [ed journal article] basically, like stating, like, you're specifically mentioned on page 12 of this journal article, your information is in paragraph two on page 12. If you have any problems with that, let us know basically" (2-35-1). As people participate in research for various reasons, following-up with them after the study concludes should be a priority for the research team.

Theme D: Participants want to confirm their understanding about the study. Participating in a digital health study may involve some risk factors that participants want to feel confident that they have fully considered before they agree to participate. Feeling confident about a study takes time. In our study, participants shared that they would like resources to assess their own understanding of a study, which may include short and easy to read summary statements, lists of frequently asked questions (FAQs), as well as brief quizzes for critical, yet easily overlooked information. Additionally, participants want access to the consent materials throughout their involvement in a study, "I'd want this information in email ideally, because a lot of times it's forms, which […] I may or may not save or download" (2-2-5).

People need time to consider their involvement in a study. Researchers should provide people with consent materials before they meet to review the content together, "give me a little paragraph about it, [so that] I could read it through thoroughly, on my time, so that […] we'll have our questions beforehand, so that they [the research team] can answer the question for us" (2-75-1). If a study involved considerable risk, prospective participants may invest considerable time preparing to meet with the research team:

"What I would like is to be given all the materials to review, whether it's videos, PowerPoints, consent, form everything in advance, and the onus would be on me to actually review everything, and then during a town hall, it's like, no holds barred, I can ask whatever I want, and hopefully, it'll benefit other people, too" (2-84-1).

A couple of participants referenced the subreddit "Explain it Like I'm Five (ELI5) as an example of how complex science topics can be communicated in simple terms. "I actually go to that subreddit [ELI5], a lot to learn about topics that you should know […] check out some of the top results, there are really, really great examples of people being able to deliver knowledge and explanation in an easy to understand and comprehensive way" (P9). Building on the ELI5 example, another participant shared how formatting decisions, similar to Wikipedia, can help to emphasize information, "I think some of those things can all be addressed in a combination of photos and large bold headings and succinct points about each one" (P8).

During the Phase 1 focus groups, participants spoke about how they like to annotate consent materials to help them learn about a study (Theme D), "let them give us the consent forms for our record […] that way we can highlight whatever questions we have, so that all of our questions will be addressed [in the consent process]" (P2). Several participants remarked that having a "question-and-answer" style consent form is "always easier" to "those long paragraphs of text" (P14). FAQs in particular can be useful, "even if I'm not reading through them all carefully, I'm at least skimming them because some may pertain to you directly" (P8).

Theme E: Participants want access to multiple and interactive ways of reviewing the material. As consent communications may include study details that are important to carefully review due to their heightened risk (Theme D), there are also other study aspects that involve less risk to the participants. Participants stressed that the design of consent communication needs to correspond with the level and types of risks associated with the study. Otherwise, an over-designed consent process may impose too much of a burden on prospective participants, such that the process may become a barrier to study recruitment.

Participants shared that they would prefer short videos about a study. Well-structured videos can communicate a lot of information, as a participant shared, "the most effective ones aren't super long, like just a few minutes […] that basically outlines the study" (P18). Watching how researchers communicate through video can promote trust in a study, "I think you kind of have to see how they are as well, how they communicate, how respectful they are, and how knowledgeable they are about the study" (P17). Social media can be a way to help people learn about research, for example, some academic researchers use social media to help people learn about the implications of specific studies, and to offer opinions and advice on a range of topics.

Some participants suggested that the short videos could be part of a multi-modal approach to consent communication, which would respond to various learning styles. "I think a better answer is having a multimodal approach […] so like a website, in addition to videos and audios you know just to be as inclusive as possible" (4-68-1). Participants discussed ways to accommodate the different learning styles and needs people may have in a consent process (Area themes 10 \& 11). "If there's like a language barrier or, someone who's visually impaired, or hearing impaired, […] just coming up with creative ways to be inclusive" (P17). Participants also shared that a "clickable" consent process can be useful "just to keep somebody engaged with the consent form, because it's really easy when you have pages of text to just get lost and bored [then] skip to the end and not even know what you're agreeing to" (P8). Several participants emphasized that learning should be central through the design of consent processes. However, participants also felt that, if the informed consent process requires more effort or is frustrating, it would deter them from participating in the study, "time is precious, and I don't want to spend more time doing this than I feel like I need to" (P5). Some participants reminded us that rather than try to design the perfect consent communication for everyone, simply asking people "how they would like to receive the information," (4-192-1) can go a long way toward demonstrating respect for participants.

Theme F: Participants need ways to keep in touch with researchers. The content and design of a consent process can help people to learn about a study, but to make an informed decision about participating, people shared that they want to feel trust in the research team. To cultivate trust, prospective participants need ways to stay connected with the research team. Prospective participants want to observe, "how they [researchers] communicate with you and how respectful they are and how knowledgeable they are about the study and how respectful they are in like executing all the steps" (4-82-1).

Some participants shared frustrating experiences communicating with researchers in the past. "Especially in more complex studies […] gradually I think of like 5, 10, 20 questions, and end up having to email the [research] team, and it's a lot of back and forth" (P11). Rather than get into a series of email exchanges, some participants preferred video conferencing, "I like these zoom discussions, they are really helpful to think […] in a small group, where we have a chance to learn more about it from the people running the study" (P15). However, responding to emails and facilitating small group discussions may sometimes be an unjustified burden for researchers.

Participants also want to feel confident that this communication about the consent materials will continue as needed throughout the study, "people might forget certain parts when signing the consent form so like as things come up along the study kind of reminding people that this is something in the consent form and, if at all, at any point you're not feeling comfortable with this now, you can like still feel free to like dropout" (4-35-1). A little appreciation

from the research team can go a long way toward promoting trust:

"And like what how it was being used and how thankful, they were, and so it kind of helped me realize like the importance of my participation and it kind of made me want to be even better about how I give like my responses and how I contribute to this study" (4-118-1).

As the study progresses, the conversation with researchers should also shift to focus on study progress, successes, and challenges. Researchers can update participants about their personal progress, "I think during the study, if, depending on exactly the I guess the parameters of the study, if you're making progress, I think [you] want to see progress and positivity, so if you had some sort of […] a weekly or quarterly email, *hey, this is the progress that you've made*, *these are the goals that you've attained* […] something like that" (1-48-1). Other participants shared that they would like to know more general information about study progress, "like a quarterly newsletter that says, like you know here's how many people have enrolled in this study and here's how they're doing" (3-138-1) and even group-level details, "I think getting like the infographic of maybe like the progress the study would be nice to come to people" (4-251-1). Returning results to study participants is another way researchers can demonstrate respect to people.

Discussion

The analysis resulted in six major themes and sixteen subthemes to guide informed consent in digital health research. Each theme might be used by researchers to reflect on the ways that they wish to communicate with prospective participants. IRB members might find it useful to reference a theme or two when communicating with researchers about aspects of a consent communication to improve. Some academic professional associations may use the themes as scaffolding for educational opportunities for their members. As the availability and requirements of funding play a non-trivial role in the conduct of research, sponsors could use the themes as part of their grant proposal review criteria, to ensure that researchers are incentivized to prioritize their respect for persons who may become participants.

At a high level, the themes offer three primary reminders toward facilitating the informed consent process:

1. Design consent processes so that they elicit informed questions from prospective participants.

Measures of "readability" such as the Flesch Reading Ease Test and the Lexile Framework for Reading are recommended tools to help researchers edit their consent content to be more accessible. Our analysis points toward another, perhaps more important indicator: questions and answers raised during the consent process. As participants in our study reflected on the provided consent materials, they shared many questions that they might have, if given the opportunity to participate. Questions ranged from concerns about data management and sharing to the feel and function of the technology in the context of their daily lives. The sheer variety of questions elicited during the focus group sessions serves as a reminder that the purpose of the informed consent process is to provide study information and answers to questions, which is challenging to do without knowing the questions that matter most to each prospective participant.

Digital health researchers can help people to imagine what their participation in a study might feel like by walking through scenarios and sharing storyboards. For instance, after sharing information about a specific study technology during a consent process, researchers might ask prospective participants to think through their day yesterday and imagine how the technology might benefit or bump up against their daily routines or disappear into the background. Digital health researchers can also ask participants to talk about their typical routines—around bedtime for example—so that during the consent process they can identify possible barriers to study participation related to existing routines. For example, as many digital health technologies incorporate active and passive data collection, researchers could ask participants to imagine how they might respond if they received a notification during certain periods of activity, such as at work, in the middle of a child bedtime routine, and early in the morning. Prompting people to reflect can help them to generate questions about their possible involvement in a study that are personally meaningful.

Rather than centering a consent process on specific language, researchers could present a variety of materials to elicit questions from prospective participants. This might include a video of the study technology in use, frequently asked questions about the technology, data flow diagrams to present how personal information is collected, stored, and shared, and so on. While consent content remains a priority for compliance purposes, the consent process can (and should) prioritize providing answers to the questions that matter to each prospective participant.

2. Compassionately help prospective participants to identify how a study technology might impact their life.

As digital literacy can be a barrier to study participation, researchers should acknowledge that prospective participants may be reluctant to share their concerns about a technology, so researchers should consider prompting participants to communicate their concerns in ways that are face-saving or preserve the dignity of the participant. Our analysis highlights a few strategies for compassionately overcoming these literacy barriers in a consent process, such as inviting prospective participants to share what they think

other people may find confusing and discussing how study results will be returned to them.

Researchers should practice asking questions that are emotionally safe for people. As shared by participants in this study, inviting people to speculate about "what other people might find confusing," is emotionally safer than asking a direct question, like "what do you find confusing," which assumes that the person is confused by something and challenges them to pinpoint the source of that confusion. By discussing "other people" the researchers allow the prospective participant to share relevant information in a way that does not expose any literacy gaps. Additionally, this rhetorical shift invites prospective participants to provide advice as a partner to the researchers.

Our analysis highlights several types of individual and group-level results that prospective participants are interested in accessing. Access to group-level research results is of value to participants who are curious about knowing what is being learned over time. The return of individual-level results is increasingly common in digital health research interventions where the technology may be used to promote physical activity or increase awareness of sleep patterns. Sharing of research results with participants is a relatively new practice and one that requires additional research to know how best to communicate research results that provide useful information to participants.

3. Communicate information in ways that reflect the values of the research team.

The consent process is a central way for people to learn about the research team before deciding to participate in a study. Our analysis highlights the importance of cultivating trust with the research team by observing how they communicate, e.g., are they respectful, do their responses offer clarity and confidence. If the process of communicating with the research team is frustrating, that may be a good indication of how participating in a study would feel. Prior research has shown that the concept of "engaged" consent is a way to practice the principle of respect for persons when a "broad" consent approach is acceptable (Bromley et al., 2020). The idea of "engaged" consent originated in the context of creating a data repository to explain to participants a priori what research questions will be posed and answered is challenging because the research questions are not known when the repository is being developed.

For studies involving a "narrow" consent that can convey specific study research questions and procedures, the need for engagement with the research team and ongoing consent communications would vary, depending on the nature and scope of the study. Take for example an observational study that involves the use of an audio recording device worn by a mom and their baby to evaluate language development. It may be important for the research team to check in with participants to assess whether the study protocol is manageable and can be adhered to in both the short and longer term of participation. These engagement practices align with the theme of keeping in touch with researchers, which can support trust building between the research team and participants.

Limitations

Through this research, we identified several approaches that have the potential of transforming the informed consent process in meaningful ways. A limitation of our study is that our sample included prospective participants who would be eligible to enroll in the larger HealthyBaby study – women of childbearing age. As a result, the participants may have been overly eager to participate, more so than average participants in research. Additionally, through prior research, we have learned that gender matters when it comes to preferences for study details needed to make an informed decision to participate in digital health research (Breese et al., 2007; Ray et al., 2011). As such, it may be that limiting participation to women of childbearing age provides a limited perspective of consent design recommendations.

The study also involved a focus-group method, which is useful for our formative research, but limits participant perspectives on consent processes to what they have experienced and could imagine experiencing in the future. Future research should consider engaging people with possible future consent processes to investigate key considerations related to privacy, data collection, virtual agents, artificial intelligence, and so on. By introducing people to possible future processes for digital consent, we might gain a deeper understanding of the risks and opportunities within the consent communication design space.

Best Practices

The literature reporting research on informed consent continues to suggest recommendations for change, like what we have learned through our focus group discussions (Corneli & Sugarman, 2017). The extent to which changes are occurring is less evident and may point to structural challenges within the research ecosystem. People considering participation in digital health research will need to develop the technology literacy and data literacy necessary to volunteer. The technologies used in digital health research may be research grade, which means that the research team has complete control over the data management including collection, storage and sharing protocols. Participants will need to know where the data they contribute will be stored and who may have access before making an informed decision to participate. In addition to data management and risk to benefit assessment, participants will need to be able to access and use the technologies consistently and be comfortable with the related privacy

limitations (Nebeker et al., 2016). To make these needs more actionable, we propose the following steps that researchers can take that are grounded in the themes reported in our results:

1. Clarify what steps will be taken to protect participant privacy.
2. Describe ways the technology can be useful to the participant, while involved in the study.
3. Describe whether/how study participants will communicate with researchers, staff, and other participants.
4. Explain about how much time and effort will be required of study participants.
5. Describe the process for providing study updates, including publications in an accessible format, during and after study closure.
6. Explain practices for how data are collected, transmitted, secured, and shared.
7. Identify ways to provide access to study information in advance so that prospective participants can review and think about what questions they may have for the research team.
8. Develop protocols that can be implemented to verify that people enrolling understand the study as described in the consent communications.
9. Develop protocols that assist the research team to create consent communications that are clear and concise.
10. Considering that people have different ways of learning, develop strategies for conveying study information using multipronged approaches. Strategies may include short videos, interactive tutorials, and ways of communicating complex concepts online.
11. Create opportunities for participants to interact with the research team.
12. When appropriate, identify how and when it may be appropriate to let participants know how they change over time as well as how they compare to other participants.
13. For longitudinal studies, consider how the research team can convey encouragement and appreciation to study participants.
14. Develop communication strategies to remind participants about what they agree to and remind them of their rights as a research participant.

Research Agenda

There is a compelling need to develop, evaluate and implement educational resources for various stakeholders involved with implementing digital health research that incorporates a new consent design. If we are to be responsive to what we heard from prospective participants, exploiting the "wiggle room" inherent in the federal regulations may be a first step. In addition, sponsors could also play an important role in enabling researchers to develop consent communications desired by those considering study participation. The sponsor's role may involve building in the time needed to engage with those who can represent the future study participant with a goal of learning what touchpoints are appropriate for facilitating informed consent for a particular study.

Other stakeholders may include professional societies, research institutions and IRBs as well as research teams and participants. For example, much of our federally funded research requires that informed consent be obtained prior to conducting research with human participants. In digital health research or, projects that involve the development of a data repository (i.e., All of Us, Bridge to Artificial Intelligence), time is needed to plan how to convey study information in a manner that is culturally aligned as well as accessible and meaningful.

Rarely do research funders support the time necessary for the research team to co-design the consent process with people like those who might consider study participation. As a result, researchers follow the IRB template and create a document that includes required study details including the purpose, procedures, risks, risk management, data management protocols, and a disclosure of whether the research leaders have a conflict of interest. With additional funding, researchers can build education into the consent process that may help participants to understand how the technologies work and where the data are flowing once collected. If the funding agencies require that more effort be made to improve the informed consent communications, then if follows that the IRBs may need to adjust expectations with respect to the use of the one-size fits all consent templates. On the other hand, if IRBs were incentivized to improve consent communications, they may be motivated to identify improvements that could be generalized beyond digital health research studies.

Educational Opportunities

Learning should be prioritized during the design of the consent communications – this means both the study information content and the process of delivering that information should promote learning about the research study. If a goal of informed consent is to assist a prospective participant in making an informed decision, our approach will need to be more human centered and responsive to the needs of people who may participate in research. Education, in this case, will need to target funding agencies that support the research such that they allocate the funding needed by the researchers to dedicate time to learning how to convey complex study information in a manner conducive to learning by people who are like those who will be engaged in the research. IRB members will also benefit

from education that elevates their awareness of how template compliance can undermine the purpose and intent of informed consent. While template compliance meets the letter of the law, so to speak, it may not result in an educated and informed participant.

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ORCID iD


Camille Nebeker https://orcid.org/0000-0001-6819-1796

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Author Biographies

Brian J. McInnis is a human-computer interaction and public policy researcher at UC San Diego who studies online discussion about civic, policy, and ethical issues in public health. Dr. McInnis earned his PhD in Information Science from Cornell University and previously studied a range of policy topics at the RAND Corporation.

Ramona Pindus' work explores the use of visual and non-visual tools in shaping communication in the context of health, policy, and complex systems. She studied public health and public administration and has over ten years of healthcare experience.

Daniah Kareem is a public health professional with experience in the realms of informed consent research and health ethics. Her professional background is rooted in healthcare, further contributes her understanding of crucial aspects of public health.

Camille Nebeker is a research ethicist and professor at UC San Diego who studies the ethical, legal and social implications of digital health approaches used in research. Dr. Nebeker leads the ReCODE Health center at UC San Diego and is Director of the UCSD Research Ethics Program.