

Foundations and Frontiers: Navigating Ethics in Digital Health Research

USING DIGITAL TOOLS TO ADVANCE BIOMEDICAL RESEARCH

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Describe key characteristics and challenges of digital health research, including the use of mobile sensors, apps, and big data for biomedical research.



Identify ethical considerations associated with participant privacy, informed consent, and the return of individual research results in digital health contexts.



Evaluate practical approaches and tools, such as digital health checklists and decision support aids, to improve consent communications and protect participant rights.

Learning Objectives



What is digital health research?

There are many sources of health data. Digital health research involves the use of one or more digital strategies or tools to gather personal health information. Sources include:

- Social media platforms

- Wearable or remote sensing devices

- Electronic health records

Digital health technology can provide personalized and *just-in-time* adaptive health interventions



Wearable
Sensors



Space Sensors



Patient-Clinician
Communication

Overview of Digital/AI in Health Research



Analyzing social media and smartphone data to detect health behaviors (e.g., physical activity, mood changes)



Predicting diagnoses using EHRs and neuroimaging



Monitoring speech and language for signs of disease and social isolation



Identifying treatment adherence patterns

New Methods = New Data

Wearable Cameras	GPS Tracking	Smart Phones	Social Media
			 <p data-bbox="1646 786 2015 829">The CORE UCSD @UCSDtheCORE - Apr 5 Rashed Al Kotob proudly represents our #COREpics team @UCSDH #PublicHealthWeek #InHealth #DigitalHealth #research #ethics #BAPM</p>
			

Ethical, Legal & Social Implications (ELSI)



Respect

Autonomy

Beneficence

Justice

Transparency

Ethical



Liability

Privacy: GDPR & CCPR

Intellectual Property

Federal Regs

Conflict of Interest

Legal



Downstream Impact

Unknown Unknowns

Sociotechnical Systems

Privacy Expectations

Return of Value

Social

What are some of the ELSIs associated with digital/AI health research?

What are the Ethical Issues?



Privacy and Data Confidentiality – sensitive health data. What can we expect from deidentification?



Informed Consent – not always needed and when it is, data literacy is needed.



Data bias - perpetuate existing health disparities. How to ensure diverse and representative data?



Values - Transparent, explainable and fair to prevent bias, stigma and discrimination.

What are the Legal Issues?



Evaluate **data protection regs** – compliance with GDPR, HIPAA



Determine **intellectual property rights** – related to data, algorithms and models



Establish **liability and accountability** framework for the system and mitigate patient harm.



Clear **data governance** policies to ensure data quality, security and integrity

What are the Social Issues?

Public Trust – we rely on people/patients to share data

Health Disparities – systems must be equitable and accessible

Digital Divide – Not all have equal access to needed resources

Cultural Sensitivity - how to authentically engage with diverse populations

What do we need to be thinking about?

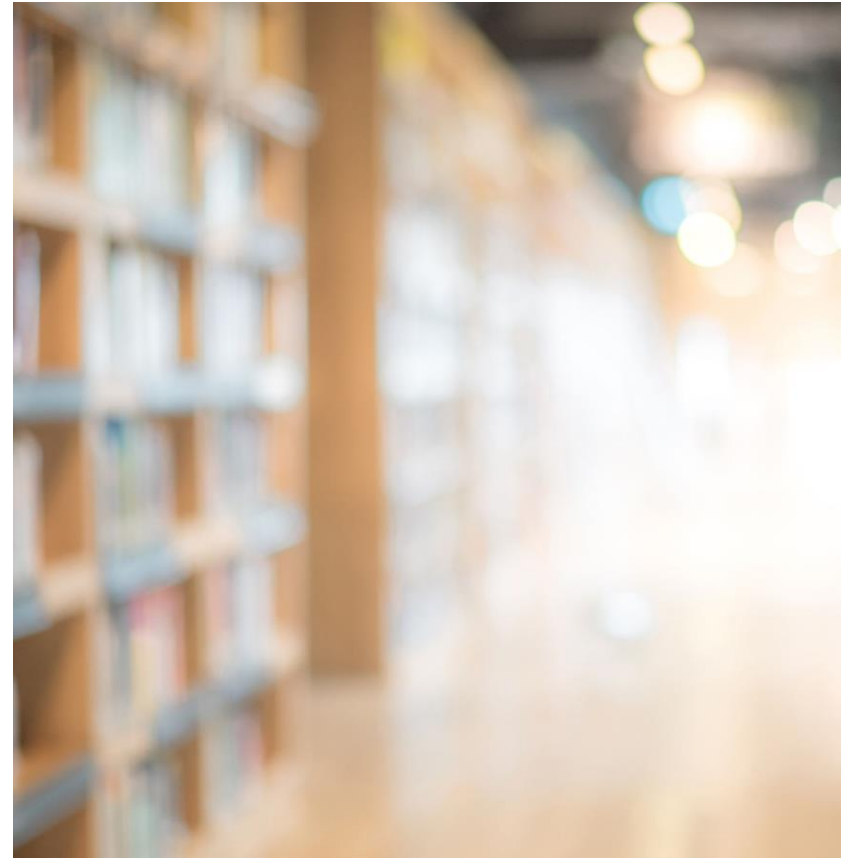
How might we prioritize the data contributor (people/patients) and the public interest in the research ecosystem?

What does governance look like throughout the collection, management and use of data when:

- Consent is only required sometimes
- Scope of use is debated
- Normative and legal implication of de-identification changes over time

Complying with the regulations/law may not be enough – how to go beyond compliance?

How to form diverse teams to conduct research and allow sufficient time for establishing infrastructure and protocols?



Ethical Oversight in Big Data Health Research



Critiques traditional ethics review processes for being ill-equipped to handle the complexities of big data research.



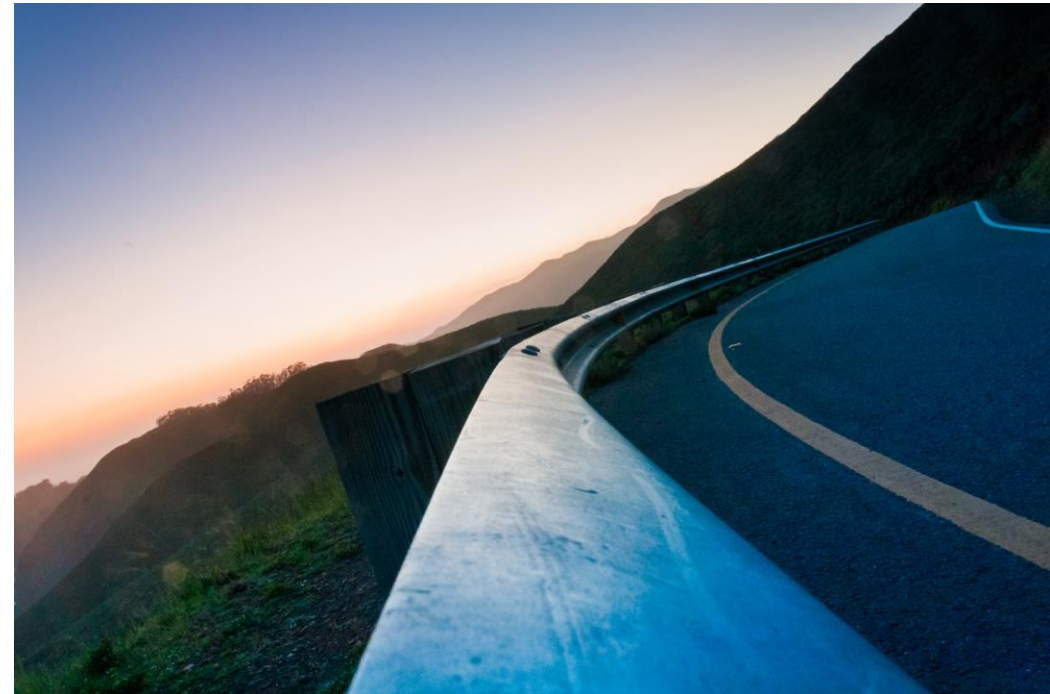
Identifies persistent challenges such as informed consent, data anonymization, and third-party data use.



Highlights the importance of trust, transparency, and participant engagement in data-intensive research contexts.

Where are the Guardrails?

- Risk assessment is challenging. What tools are available to assist?
- Our current methods of obtaining informed consent are not effective. Can GenAI help?
- Data management practices are complex – can GenAI help to unpack privacy policy language?



A paradigm change
requires a commitment
and dedicated resources

Research: Informing Informed Consent

Name _____

Signature _____

Date _____

The Common Rule: US Federal Code §46.116(a)(5)

(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.”

Informed consent is driven by templates

- Template based process
- Common recommendations
 - 6th-8th grade reading level
 - Sometimes, incorporate visual and other media
 - Sometimes ask stakeholders to prototype the study materials
- Research teams and IRBs need to lead the change they want to see

UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

[include the below note when the study will involve children or adults unable to consent for themselves. Otherwise delete.]
Note: In this consent the word "you" refers to the person being considered for enrollment in the study described. This may be you as the reader of this document, a person for whom you are serving as the Legally Authorized Representative (LAR) or surrogate, or your child.

1. Study Title and Number
Title: [insert title of study]
Study #: [insert study number from Kuail]

2. Principal Investigator
[insert PI name, title, and department/institute/center]

3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number
[insert PI phone number, research team phone number, and emergency contact number, if different]

4. Study Sponsor
[insert name of study sponsor or remove if not applicable], the study sponsor, is paying UC San Diego [or name of institution conducting the research when UCSD serves as the IRB of record] to conduct this research study.

5. Study Overview

This research study is being conducted to [briefly describe in lay terminology the reason why the study is being conducted].

We are inviting you to participate in a research study because [briefly summarize the condition or circumstance that makes an individual eligible for the research. Do not provide a list of inclusion/exclusion criteria].

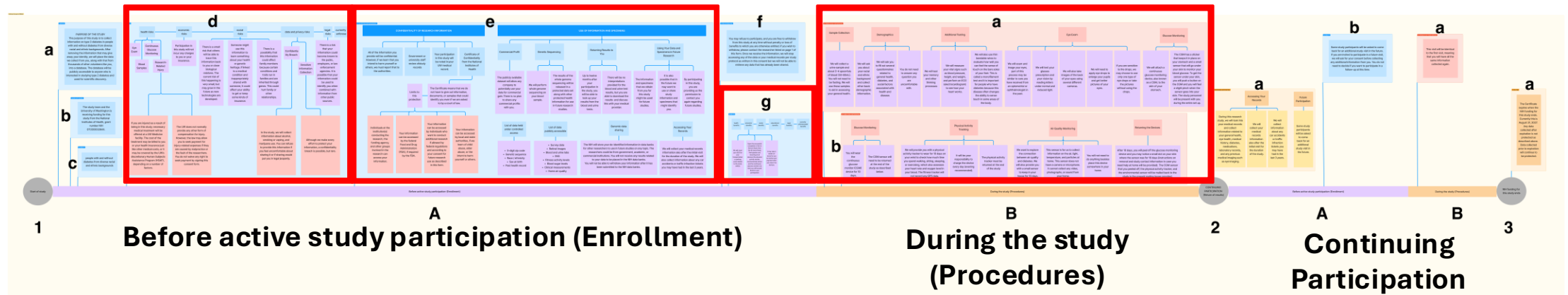
This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to [complete with brief statement, no more than 3 sentences. Secondary/exploratory objectives need not be included.].

Version Date: [update this for document control] Page 1 of 20

Study decision-making timeline (highlights)



1. START OF STUDY

A. Before active study participation (Enrollment)

- a. Purpose
- b. Source of Funding
- c. Eligibility
- d. RISKS
- e. DATA COLLECTION AND MANAGEMENT
 - i. Confidentiality of research information
 - ii. Use of information and specimens
- f. Other information
- g. BENEFITS

B. During the study (Procedures)

- a. In-person study participation
- b. At home study participation

2. CONTINUING PARTICIPATION (Return of results)

A. Before active study participation (Enrollment)

- a. Continuing participation
- b. Eligibility

B. During the study (Procedures)

- a. In-person study participation

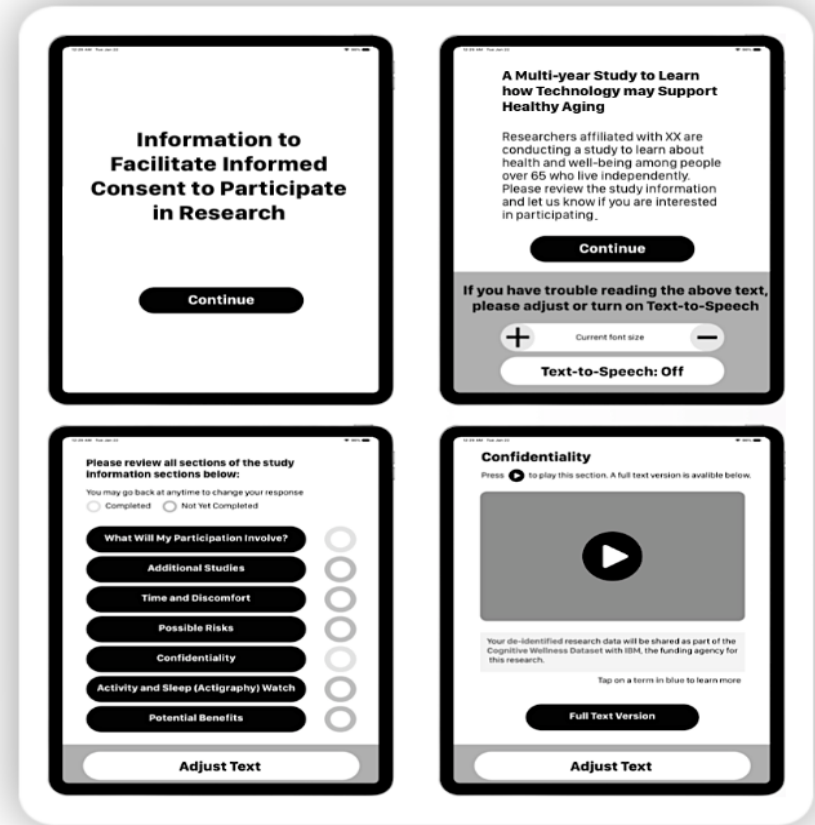
3. END OF STUDY

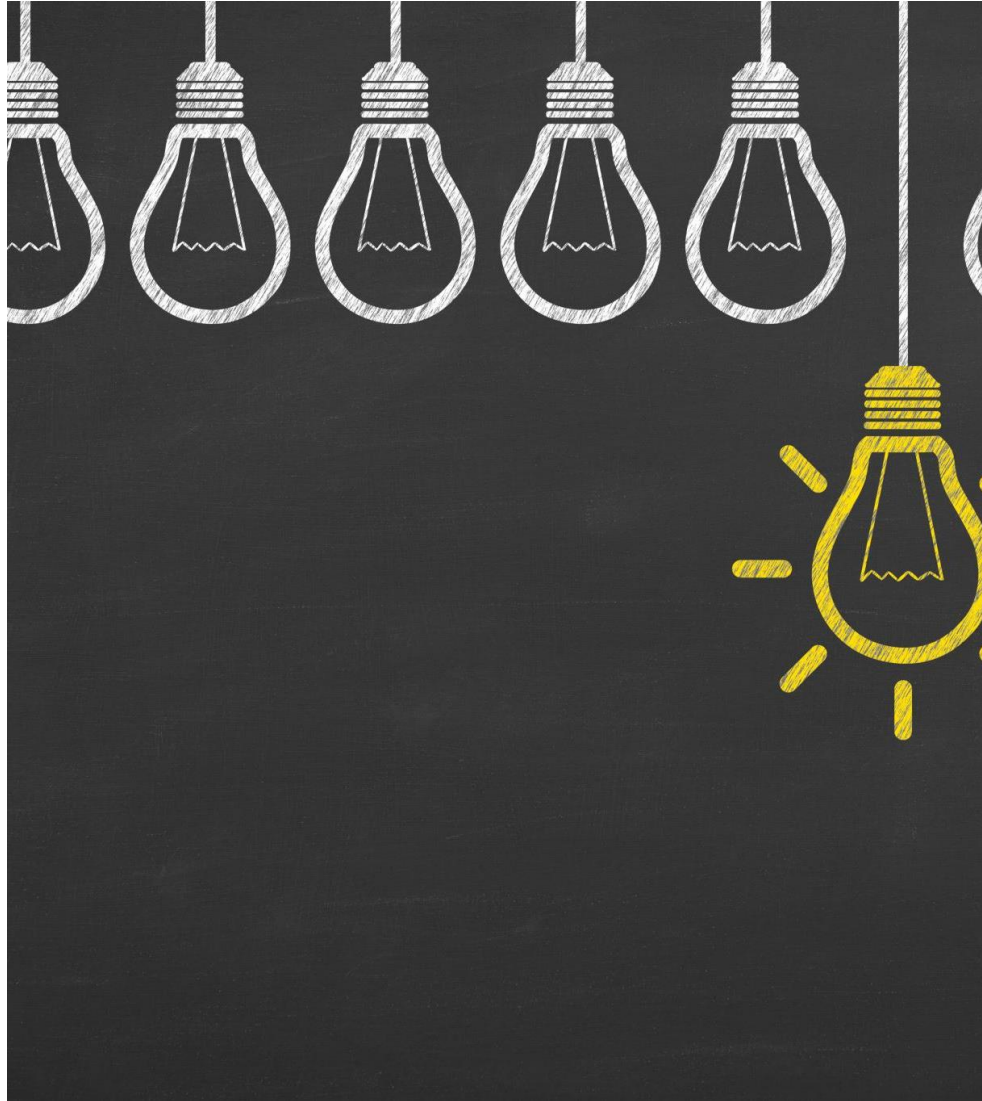
- a. NIH funding for this study ends

Human centered design of informed consent



- Who is conducting the study
- Why is the study being done





New assumptions for consent informed by our research

1. Informed consent should cultivate trust in science
2. People want a concise, but personalized consent process
3. Digital consent processes are not inherently better (and can add risk)
4. Data management practices need to be visible.

1. Informed consent should cultivate trust in science

Participants want

- to know about technology
- to learn about specific expectations for participation
- to understand data collection, protection, and sharing practices
- to confirm that they understand the consent material
- access to multiple and interactive ways of reviewing the consent materials
- ways to keep in touch with researchers

Study methods: Four focus groups with prospective participants to explore preferences around the design of digital health consent processes (N=19).



2. People want a concise, but personalized consent process

Factors that people value in consent materials:

- Shorter consent materials are preferred, but people want personally relevant details.
- People value more detail about study risks, than other sections of a consent form.
- Subgroups based on gender, age, physical activity, and interest in the study all play into participant preferences for more and less detail.
- Our analysis highlights how some subgroups, such as Hispanic/Latino participants, felt that the consent materials were inadequate.

Study methods: Participants compared 31 statements from a consent form with variations improved for readability (N=79), logistic regression analysis to identify preferences by participant demographic and background characteristics.

3. Digital consent processes are not better (can add risk)

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

- What should happen if people skip or skim sections?
- How might researchers protect people from third-party access to their data prior to consent?
- If consent materials are updated regularly, how might researchers manage version control?
- How might ethics review boards consider the data collected during a consent process?
- What resources might researchers use to maintain clear, consistent, and compliant communications with a potentially large audience of prospective study participants?

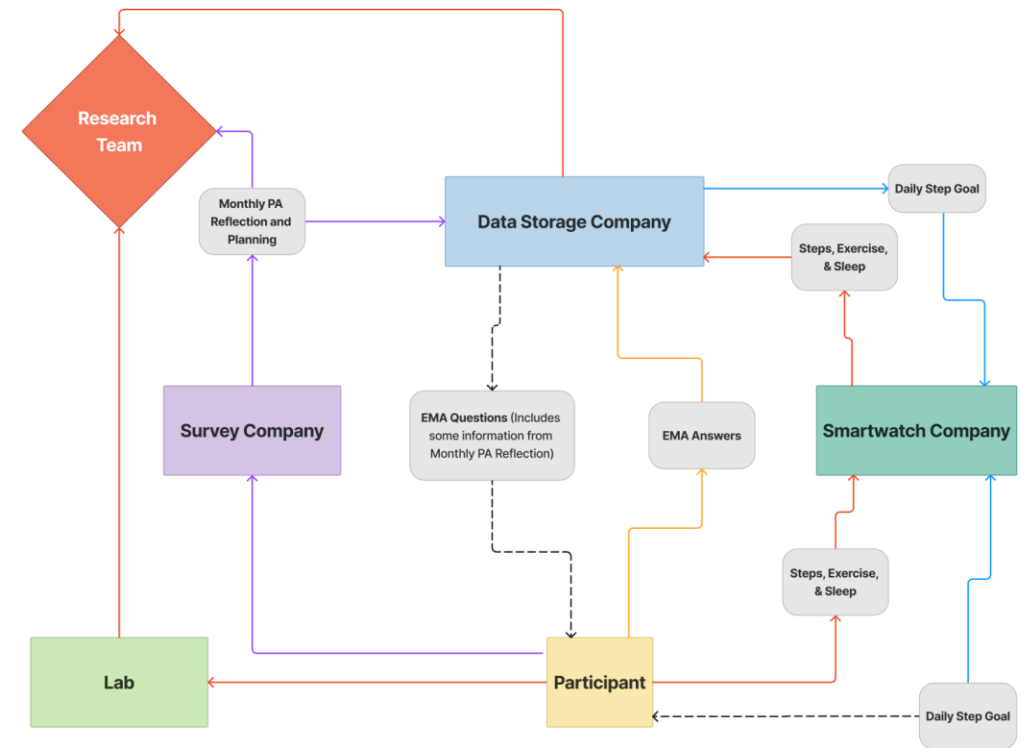
Study Method: Participants considered a series of futuristic consent processes in a "design speed-dating" method (N=21), applying analytic memo writing to identify five principles to improve digital informed consent: be concise, promote transparency, value time and effort, cultivate trust, and navigate platform risks.

4. Data management protocols needs to be visible

Dataflow diagrams can supplement a text-based consent.

- Diagrams need to be clear, simple, accessible, and participant-centered.
- Our analysis found that dataflow diagrams helped participants to raise new questions about the data collection and sharing activities of third-party services.
- Participants suggest that generative AI could be used to help initially create a dataflow diagram, but researchers, panels of peers, and ethics review boards should be involved in the process of evaluating dataflow diagrams for use in consent processes.

Study Method: Participants in a focus group study reviewed design decisions related to incorporating dataflow diagrams of digital health studies into an informed consent process (N=34), applying a grounded theory approach to identify themes.



Created by

Open AI. (2023).



Tools to Support Ethical Decision-making

Digital Health Checklist Tool for Researchers

Development of a decision-making checklist tool to support technology selection in digital health research

Camille Nebeker , Rebecca J Bartlett Ellis, John Torous

Translational Behavioral Medicine, ibz074, <https://doi.org/10.1093/tbm/ibz074>

Published: 23 May 2019

“ Cite

 Permissions

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Abstract

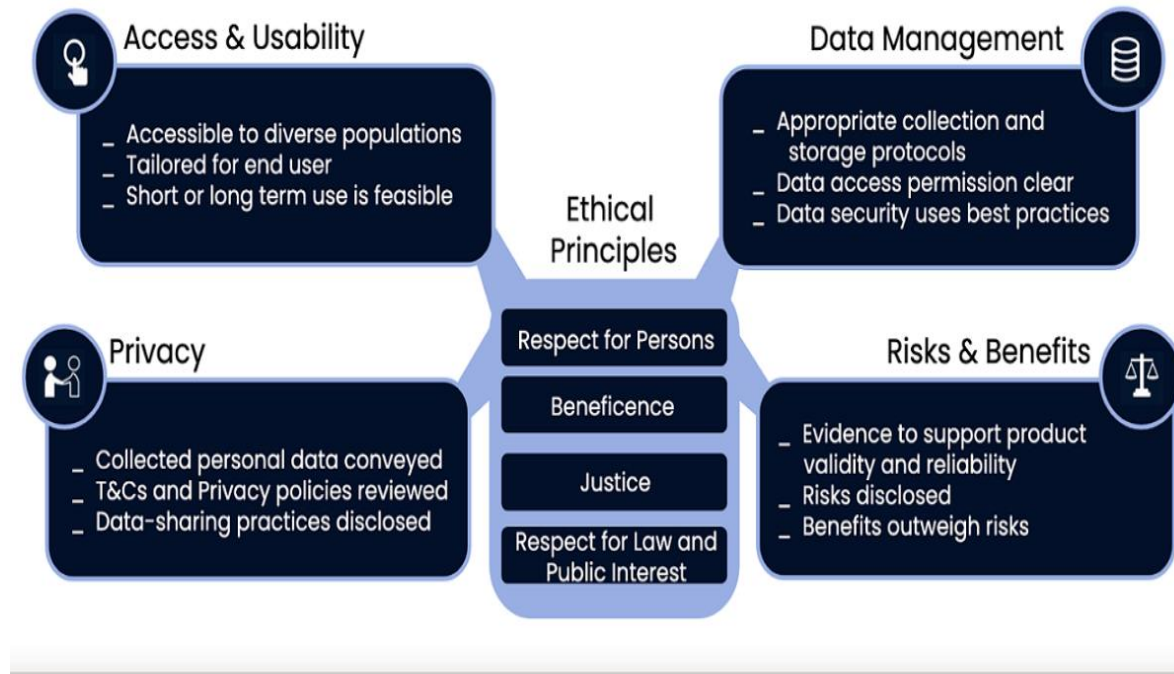
Digital technologies offer researchers new approaches to test personalized and adaptive health interventions tailored to an individual. Yet, research leveraging

Digital health decision support framework

While digital health research is ripe with opportunities, there are many challenges associated with using these technologies.

Key challenges include:

1. evaluating whether study participants can access and use the technology,
2. identifying study risks and benefits,
3. establishing ethical data management practices, and
4. protecting participant privacy.



Access and Usability

The domain of *access and usability* is about the product design and whether end-users are able to use the tool.

- How does it work?
- How that this information communicated to the user (informed consent or terms of service)?
- Has it been used with the target population? Are accessory tools needed (smartphone, internet access)?
- Can the product can be used both short and long-term?

Access & Usability

Respect for Persons		Beneficence	
Contract provides:			
Relevant information within Terms of Service/Privacy policy in plain language?	<input type="checkbox"/>	Includes a plan for return of group and individual study information?	<input type="checkbox"/>
Access to definitions?	<input type="checkbox"/>	Study design includes features to increase access and usability for older adults?	<input type="checkbox"/>
Access to visual and audio versions of information?	<input type="checkbox"/>	Short and long-term use has been or will be tested with older adults?	<input type="checkbox"/>
Possibility of bystander involvement?	<input type="checkbox"/>	Rights of all stakeholders are considered?	<input type="checkbox"/>

Justice		Respect for Law and Public Interest	
Device or App was tested with older adults?	<input type="checkbox"/>	AI is accountable?	<input type="checkbox"/>
Requires internet?	<input type="checkbox"/>	Algorithms are documented and transparent?	<input type="checkbox"/>
Requires smartphone?	<input type="checkbox"/>		
AI trained on data inclusive of older adults?	<input type="checkbox"/>		

Privacy

Privacy is about the personal information collected and expectations of the patient or participant to keep information secure. If shared:

- What is collected?
- What is shared?
- Why is it shared?
- What control does the end user have?

Privacy

Respect for Persons **Beneficence**

Contract clearly conveys:

Personal information collected?	<input type="checkbox"/>	Privacy expectations are respected?	<input type="checkbox"/>
Data sharing plan?	<input type="checkbox"/>	Participant data are not shared or sold to a 3 rd party?	<input type="checkbox"/>
Privacy policy risks?	<input type="checkbox"/>	Participant contact information is not shared/exploited?	<input type="checkbox"/>

Justice **Respect for Law and Public Interest**

Bias is managed to reduce...

Economic harm?	<input type="checkbox"/>	Increase trust?	<input type="checkbox"/>
Social harm?	<input type="checkbox"/>	Protect privacy?	<input type="checkbox"/>
Discrimination?	<input type="checkbox"/>		
Profiling?	<input type="checkbox"/>		

Data Management

Data management includes how data are collected, stored and shared and the extent of incorporation within other systems.

- What is collected?
- What is shared?
- Why is it shared?
- What control does the end-user have?
- Interoperability?

Data Management

Respect for Persons		Beneficence	
Contract clearly conveys:			
Data collection process?	<input type="checkbox"/>	Data collection by party external to the research team?	<input type="checkbox"/>
Data storage and security?	<input type="checkbox"/>	Potential of data collected on or about a bystander (caregiver)?	<input type="checkbox"/>
Who will have data access?	<input type="checkbox"/>	Data are accessible to the patient?	<input type="checkbox"/>
Protocols for data sharing?	<input type="checkbox"/>	Data are transferrable to the EHR?	<input type="checkbox"/>
		Data ownership is clear?	<input type="checkbox"/>

Justice		Respect for Law and Public Interest	
System vulnerabilities are publicly disclosed?	<input type="checkbox"/>	Data encryption meets expected standards?	<input type="checkbox"/>
Data are not used to target groups or people?	<input type="checkbox"/>	Storage is HIPAA and CFR compliant	<input type="checkbox"/>
		Data are deidentified?	<input type="checkbox"/>

Risks and Benefits

The goal of this domain is to evaluate the types of possible risks as well as the extent of possible harm.

- Types of harm?
- Severity?
- Duration?
- Intensity?
- AI Accountability and Transparency?

Assessment of risks and benefits is influenced by the evidence available to support the reliability of the product, risk mitigation strategies and recognition of unknown risks.

Risks & Benefits

Respect for Persons		Beneficence	
Contract clearly conveys:			
Risks and risk management strategies?	<input type="checkbox"/>	Product is respectful of privacy preferences?	<input type="checkbox"/>
Evidence?	<input type="checkbox"/>	Evidence to support tech reliability/validity?	<input type="checkbox"/>
Unknown risks?	<input type="checkbox"/>	Evidence is peer-reviewed?	<input type="checkbox"/>
Possible benefits to the person, people like them and to society?	<input type="checkbox"/>	Risks are known and mitigated?	<input type="checkbox"/>
		Risks are unknown and acknowledged?	<input type="checkbox"/>
		Potential benefits outweigh possible risks of harm?	<input type="checkbox"/>

Justice		Respect for Law and Public Interest	
Legal harms are known?	<input type="checkbox"/>	Data and privacy protections are compliant?	<input type="checkbox"/>
Potential risk of discrimination is transparent?	<input type="checkbox"/>		
Risks of harm no greater for 05+ demographic?	<input type="checkbox"/>		





Using the DHC to Improve Consent Communications

METHODS article

Front. Digit. Health, 15 July 2021
Sec. Human Factors and Digital Health
Volume 3 - 2021 | <https://doi.org/10.3389/fdgth.2021.690901>

This article is part of the Research Topic
Responsible Digital Health
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Applying a Digital Health Checklist and Readability Tools to Improve Informed Consent for Digital Health Research

 Camille Nebeker^{1,2*}  Maryam Gholami^{1,2}  Daniah Kareem^{1,2}  Emily Kim¹

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² Design Lab, University of California, San Diego, La Jolla, CA, United States

Background: As research involving human participants increasingly occurs with the aid of digital tools (e.g., mobile apps, wearable and remote pervasive sensors), the consent content and delivery process is changing. Informed consent documents to participate in research are lengthy and difficult for prospective participants to read and understand. As the consent communication will need to

How might we communicate...

What is real time data?

How does a personalized algorithm work?

How is my health data transmitted and stored in a cloud?

Who has access to data collected by the device?

What information about me is shared?

Table 3

Four domains of DHC tool	Prompts for each domain	Yes	No	N/A	
Access and usability	1. An explanation about the technology used in the study that helps one to understand: What it does	X			
	2. An explanation about the technology used in the study that helps one to understand: Why it is being used	X			
	3. An explanation about the technology used in the study that helps one to understand: How it works	X			
	4. Plain language is used to describe the commercial vendor agreements: Terms of Service			X	
	5. Plain language is used to describe the commercial vendor agreements: Privacy policy			X	
	6. Relevant definitions provided using plain language	X			
	7. Access to visual and audio versions of information, if these alternatives are available	X			
	Risks and benefits	1. A description of the type of potential harm including: Physical harm (e.g., skin irritation)	X		
		2. A description of the type of potential harm including: Psychological harm (e.g., distress)	X		
		3. A description of the type of potential harm including: Economic harm (e.g., cost that the participants might incur as a result of using the technology)			X
		4. Economic harm (e.g., cost that the participants might incur as a result of using the technology)			X
		5. A description of the type of potential harm including: Unknown harm (Even when these harms remain unknown - a statement acknowledging that there might be harms that are unknown included)	X		
6. For potential harms a description the known or unknown: Severity				X	
7. For potential harms a description the known or unknown: Duration		X			
8. For potential harms a description the known or unknown: Intensity		X			
9. Strategies for minimizing risks		X			
10. Strategies for managing risks		X			
11. Statement that indicates: Possible benefits from knowledge gained during the study		X			
12. Statement that indicates: Benefits that could be derived by the participant related to the technology		X			
Privacy	1. Nature of personal information collected by the technology	X			
	2. Purpose for which personal information is collected by the technology			X	
	3. Extent of personal information collected by the technology (specific/inclusive list of personal information that will be collected by the technology)	X			
	4. How individual-level data will be shared and with whom, and if this might change in the future after the study			X	
	5. Whether personal data entered and stored in the technology will be de-identified			X	
Data management	1. Notification if there is a possibility of hardware involvement	X			
	2. Practices for Data security of the data that is collected by the technology	X			
	3. Practices for Data sharing with other researchers	X			
	4. Practices for Data transfer from technology to other storage	X			
	5. Practices for Data storage of data that is collected by the technology	X			
	6. Information about who will have access to data collected by the technology	X			
	7. Whether the research data are controlled by the research team or a third party	X			
	8. Whether the participant will have access to individual level data collected via the technology	X			
	9. Whether the participant will have access to individual level data collected via the technology	X			
	10. Whether the participant will have access to group level data collected via the technology	X			

TABLE 3. Digital health checklist consent blueprint: et principle "respect for persons" across four domains.

Four domains of DHC tool	Prompts for each domain	Yes	No	N/A	
Access and usability	1. An explanation about the technology used in the study that helps one to understand: What it does	X			
	2. An explanation about the technology used in the study that helps one to understand: Why it is being used	X			
	3. An explanation about the technology used in the study that helps one to understand: How it works	X			
	4. Plain language is used to describe the commercial vendor agreements: Terms of Service			X	
	5. Plain language is used to describe the commercial vendor agreements: Privacy policy			X	
	6. Relevant definitions provided using plain language	X			
	7. Access to visual and audio versions of information, if these alternatives are available	X			
	Risks and benefits	1. A description of the type of potential harm including: Physical harm (e.g., skin irritation)	X		
		2. A description of the type of potential harm including: Psychological harm (e.g., distress)	X		
		3. A description of the type of potential harm including: Economic harm (e.g., cost that the participants might incur as a result of using the technology)			X
		4. Economic harm (e.g., cost that the participants might incur as a result of using the technology)			X
		5. A description of the type of potential harm including: Unknown harm (Even when these harms remain unknown - a statement acknowledging that there might be harms that are unknown included)	X		
6. For potential harms a description the known or unknown: Severity				X	
7. For potential harms a description the known or unknown: Duration		X			
8. For potential harms a description the known or unknown: Intensity		X			
9. Strategies for minimizing risks		X			
10. Strategies for managing risks		X			
11. Statement that indicates: Possible benefits from knowledge gained during the study		X			
12. Statement that indicates: Benefits that could be derived by the participant related to the technology		X			
Privacy	1. Nature of personal information collected by the technology	X			
	2. Purpose for which personal information is collected by the technology			X	
	3. Extent of personal information collected by the technology (specific/inclusive list of personal information that will be collected by the technology)	X			
	4. How individual-level data will be shared and with whom, and if this might change in the future after the study			X	
	5. Whether personal data entered and stored in the technology will be de-identified			X	

Digital Health Checklist Risk Management Tool

Alan Card, PhD

San Diego State University

Risk = Likelihood x Consequence

...for an event that is not certain to occur.

Use of the DHC-RM Toolkit was associated with a large and statistically significant increase in the number of risks identified (a mean of 14 additional risks identified in Phase 2 for the toolkit vs. 0.26 for current practice).



Will an Apple Watch or Fitbit make you lose weight? Don't count on it.

Researchers found that wearing a fitness tracker doesn't necessarily give people the motivation to change their behavior. And for some, it might have the opposite effect.



By Geoffrey A. Fowler

February 7, 2023 at 12:30 p.m. EST



Fitness tracking app Strava gives away location of secret US army bases

Data about exercise routes shared online by soldiers can be used to pinpoint overseas facilities

● **Latest: Strava suggests military users 'opt out' of heatmap as row deepens**



📍 A military base in Helmand Province, Afghanistan with route taken by joggers highlighted by Strava. Photograph: Strava Heatmap

Identifying hazards is crucial... but severity matters, too

TaCoS and Privacy Policies



WHAT IS OUR RESPONSIBILITY WHEN USING DIGITAL AND AI PRODUCTS FROM 3RD PARTY VENDORS IN RESEARCH?

Our Team

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PRISM Study: Privacy Policy Comparison

From your expertise and experience reviewing privacy policies, conduct a comprehensive comparison of the two privacy policies. Differences between the two versions of the documents have been highlighted. Review side-by-side highlighted versions of the privacy policy documents.

NOTE: Diffchecker was the tool used to make the comparison between versions.

11:24 AM Privacy Policy | Dexcom

DexCom Sweden AB
DexCom Deutschland GmbH
DexCom International Limited, Nicosia, Zweigniederlassung Hong
Kong
Nintamed Handels GmbH
Dexcom Asia Pacific Operations Pte. Ltd.
Dexcom Malaysia Operations Sdn. Bhd.
Dexcom Lithuania, UAB

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WHAT, WHEN AND WHY WE COLLECT AND PROCESS PERSONAL INFORMATION ABOUT YOU

We may collect and process your Personal Information as described below. If you are in the United States, refer to our [Notice of Privacy Practices](#).

We may collect and process:

- **Site Information**, which means information you input into, or is otherwise associated with your access and which may constitute Personal Information, to any of our websites. Site Information includes without limitation information about the devices, apps, internet service, IP address, and browsers that you use to access our website; your online browsing behavior such as the sites you visit before and after visiting our websites, your activities on our site including the pages you view, how long you view them, product descriptions read, forms submitted, videos watched, shopping cart contents, and your clicks on our site pages; and, the passwords, security answers, and your user preferences that you provide to us. Site Information does not include Account Information, Communications Information, or Order Information (described below).

WHEN: We may collect Site Information when you access any of our websites (including our online store).

WHY: We collect and otherwise process Site Information to:

- Tailor your experience when accessing or using our websites;
- Operate and manage our business (including developing, maintaining and supporting our Products and Services);
- Provide you marketing and information about our Products and Services that we think may interest you (if you have not opted out of receiving marketing or, where an affirmative opt-in is required under applicable to law, you have affirmatively opted in to receive marketing);
- Comply with applicable law;
- Establish, exercise or defend our legal claims and rights and;

11:24 AM

11:24 AM Privacy Policy | Dexcom

Dexcom Privacy Notice

Last Updated July 2024

[Who We Are](#) | [Purpose of this Privacy Notice](#) | [Personal Data Collected, Purposes, and Recipients](#) | [Special Note to Individuals in the United States](#) | [Marketing, Cookies, and Analytics](#) | [Service Providers and Third Parties](#) | [Your Rights Regarding Your Personal Data](#) | [Sale/Transfer of Personal Data](#) | [How Long Your Personal Data Will Be Kept](#) | [Transfer of Personal Data](#) | [Changes to this Privacy Notice](#) | [Contact Us](#) | [Consumer Health Data Privacy Policy](#)

Who We Are

Dexcom, Inc. and its directly or indirectly controlled affiliate(s) or subsidiaries, listed [here](#) (Dexcom, we, our, or us) value your privacy and the protection of your Personal Data. This Privacy Notice (Notice) explains how we collect, store, use, share, transfer, delete, and otherwise process information collected from or about you known as Personal Data (defined further below in this Notice). As an international company, Dexcom has multiple legal entities in different countries that may be responsible for the Personal Data they process, and we process Personal Data in accordance with these laws.

Purpose of this Privacy Notice

This Notice describes the types of Personal Data that Dexcom may collect or process, how we may use and disclose that Personal Data, and how you may exercise any rights you may have regarding our processing of your Personal Data.

This Notice applies to Personal Data collected or processed by us:

- Through online activities and services we offer through this and other of our websites, our online store, web surveys, newsletters, applications, email, online messaging services or channels, including online "chats" with live individuals and artificial intelligence, through social media, through our telephone customer service centers, through email or SMS/text messages, and otherwise (Online Services);
- Through your account and through our products and services, whether provided directly to you or your patient, or if you are a patient, through your doctor, hospital, medical treatment facility, or other healthcare provider (Healthcare Provider), including the Stetis Glucose Biosensor System, Dexcom G7S CGM System, Dexcom G6S CGM System, Dexcom ONE CGM System, Dexcom G5S CGM System, Dexcom G6 Pro, Clearly Choic and our mobile apps such as Dexcom CM7x, Dexcom Share, Stetis by Dexcom app, the Dexcom ST app;

11:24 AM

Response 1	Response 2	Response 3
Rating: 3 - Slightly Beneficial	Rating: 6 - Moderately Harmful	Rating: 3 - Slightly Beneficial
<p>Differences Between the Two Documents:</p> <ul style="list-style-type: none"> The new version provides in-depth breakdown of different categories of data subjects and explains data collected from each category. <p>Manageability of Harm (Likelihood & Magnitude):</p> <ul style="list-style-type: none"> The new version appears to be giving more information to the users rather than constitute a change in practices. The harm must be managed by strong policies around sharing of data and security of data. <p>Feasible Mitigation Strategies:</p> <ul style="list-style-type: none"> Development of use policies and regular assessments of security protocols are feasible. <p>Summary of Changes in Data Collection:</p> <ul style="list-style-type: none"> The differences appear to be in providing more information and being more transparent with different categories of data subjects rather than changes to practices themselves. The new notice provides in-depth information about data processed for clinical trials and applicants/employees. 	<p>Differences Between the Two Documents:</p> <p>Structure & Scope:</p> <ul style="list-style-type: none"> Doc A categorizes data by source (e.g., "Site Information," "Account Information," "Use Information"). Doc B organizes data by data type (e.g., "Identity and Contact," "Health," "Technical," etc.), presenting more structured tables and broader categories. <p>Detail and Specificity:</p> <ul style="list-style-type: none"> Doc B significantly expands on the types of data collected, including more granular examples (e.g., heart rate, X-rays, telehealth session recordings, employment history, training enrollment, etc.). Doc A includes some of these elements but is less exhaustive and consistent in naming and defining them. <p>Sensitive Data Classification:</p> <ul style="list-style-type: none"> Doc B marks sensitive data explicitly with a caret (^) and explicitly acknowledges biometric, genetic, and geolocation data as sensitive. Doc A refers to "health data" generally but does not mark sensitive categories as distinctly. 	<p>Differences Between the Two Documents:</p> <p>The 2024 policy (DocB) expands significantly on the types of Personal information collected compared to the 2021 policy (DocA):</p> <ul style="list-style-type: none"> Additional data categories: The 2024 policy introduces a comprehensive categorization system with detailed tables for different user types, while the 2021 policy used a more narrative approach with less structured categories. <p>Expanded scope: The 2024 policy explicitly mentions new data types including:</p> <ul style="list-style-type: none"> Video, audio, and recorded information (including call recordings) More detailed health information (genetic information, thresholds, pathologies) Location data (which was less explicit in the 2021 version) Expanded demographic information (pregnancy status, ethnicity) More detailed technical information collection <p>User-specific collection: The 2024 policy segments data collection by user type (Online Users, Patients, Healthcare Providers, etc.) with specific tables for each, making the scope of</p>

What supported your preference choice?

* must provide value

- Content
- Style
- Both content and style
- Something else

Are there any differences between the ratings?

- Yes
- No

Are there any scores that you find concerning, confusing, or inconsistent? Please explain.

* must provide value

It's interesting that Response 2 rates the changes to the policies as moderately harmful, while the other two responses rate changes as slightly beneficial.

Please rank the response accuracy from 1 to 3, with 1 being the most accurate to 3 being least accurate.

Each item must be assigned a unique rank; duplicate rankings are not permitted.

Response 1	Response 2	Response 3
<input type="radio"/> 1	<input checked="" type="radio"/> 1	<input type="radio"/> 1
<input type="radio"/> 2	<input type="radio"/> 2	<input checked="" type="radio"/> 2
<input checked="" type="radio"/> 3	<input type="radio"/> 3	<input type="radio"/> 3

Please rank the response comprehensiveness from 1 to 3, with 1 being most comprehensive to 3 being least comprehensive.

Each item must be assigned a unique rank; duplicate rankings are not permitted.

Response 1	Response 2	Response 3
<input type="radio"/> 1	<input type="radio"/> 1	<input checked="" type="radio"/> 1
<input type="radio"/> 2	<input checked="" type="radio"/> 2	<input type="radio"/> 2
<input checked="" type="radio"/> 3	<input type="radio"/> 3	<input type="radio"/> 3

Please rank the response preference from 1 to 3, with 1 being the most preferred to 3 being least preferred.

Each item must be assigned a unique rank; duplicate rankings are not permitted.

Response 1	Response 2	Response 3
<input type="radio"/> 1	<input checked="" type="radio"/> 1	<input type="radio"/> 1
<input type="radio"/> 2	<input type="radio"/> 2	<input checked="" type="radio"/> 2
<input checked="" type="radio"/> 3	<input type="radio"/> 3	<input type="radio"/> 3

PRISM Study Aim 1 – Privacy Policy Review Comparisons

PRISM Study Aim 2 -
Co-Designing
Improved Privacy
Policy
Communications

EVENT ON MARCH 10, 2025

PRIVACY POLICY DESIGNATHON



ARE PRIVACY
POLICIES A BLIND
SPOT IN DIGITAL
HEALTH RESEARCH?

 ReCODE|health

SCAN TO KEEP
IN TOUCH



This privacy policy (this "Policy") was last updated on June 14, 2022.

Talkspace ("we", "our", "us", "Talkspace") takes your privacy seriously, and we want you to know how we collect, use, share and protect your information.

Introduction

Our proprietary technology platform uses advanced data-driven tools to personalize your care, and to enhance evidence of care, care continuity, outcomes metrics and data-based learnings. We provide mental health professionals with insights and capabilities to drive improved and measurable clinical outcomes for patients receiving virtual therapeutic services on our platform. You can access our platform via the website or through our mobile application available in the app stores ("App").

When you enroll, inquire about enrolling for or use of Talkspace Services (as defined below), we keep a record of medical information that you provide to us or your therapist as well as any medical information that Talkspace employees or independently contracted therapists provide to you via our platform (such as information on and related to your diagnosis). Medical information means any information that:

- identifies you; and
- relates to your past, present, or future physical or mental health, treatment, the provision of health care services or payment for treatment.

This includes medical history, diagnoses, treatments, current medical condition, and use of prescription medications. If you are a US subscriber to Talkspace services, your personal information in our possession is protected health information ("PHI") protected by the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), and the applicable provisions of the Health Information Technology for Economic and Clinical Health ("HITECH") Act. In addition to this Privacy Policy, the HIPAA **Notices of Privacy Practices** of Talkspace or your Talkspace Provider apply to your PHI.

This Policy explains Talkspace's practices where we process "personal data", which is information that relates to an identified or identifiable individual. To "process" or "processing" means the use of personal data including, collecting, recording, storing, using, analyzing, combining, transferring, disclosing, or deleting.

We reserve the right to change the terms of this Privacy Policy at any time by posting those changes in revisions to this Privacy Policy, so that you are always aware of our processes related to collection, use and disclosure of information. We urge you to check here for any updates to this Privacy Policy from time to time. Unless otherwise indicated, any changes to this Privacy Policy will apply immediately upon posting to the Website or the App.

- What is included in this Policy?
- Personal Data We Process & How We Use It
- Using the Talkspace App
- Advanced Data Processing
- Research

Aim 2 Overview

Objective: Facilitate stakeholder co-design activities to improve communication of third-party privacy policies in digital health research

Core Challenge:

Privacy policies are:

- Complex legal documents
- Difficult to interpret for researchers, IRB members, and participants
- Critical for informed consent and risk assessment
- Inconsistent across platforms and technologies

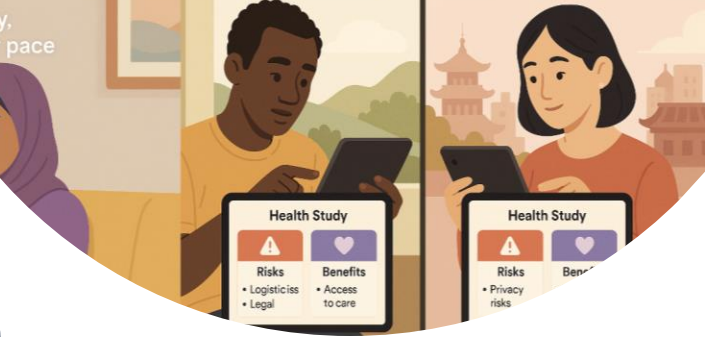
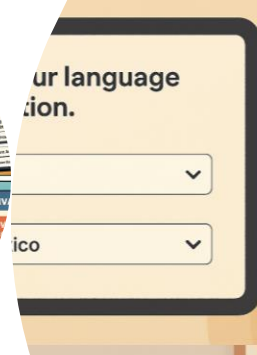
Project Status:

Complete data collection and preliminary analysis for Phase 1 (Workshop)

Beginning Phase 2 (Survey)

Prototype Ideas

1. **A policy scoring app** - transforming users from “Policy Learners” into “Policy Makers”
2. **The Rocket Data app** – facilitates creating a personalized “data risk profile”
3. **A gamified experience inspired by platform games** - navigating a game-based journey through core privacy topics
4. **An interactive, closed-loop consent tool** - outlines user rights, including real-time alerts and control over third-party data access (opt-in)
5. **A tool presents risks and benefits through multiple formats** – sensitive to risks and benefits variation across cultural and regional contexts
6. **IRB workflow tool** - helps researchers align data needs with device capabilities



We are conducting a study on data management practices in digital health research, focusing on privacy policy communication.

We are inviting up to 150 individuals **involved in digital health research** to complete a 30-minute online survey.

The survey explores strategies to simplify and communicate data management practices described in privacy policies.

PRISM Survey Opportunity

Applied to Research



Pros: How might researchers use GenAI

Explore how it might help to simplify informed consent communications

Review and synthesize privacy policies for data management risks

Conduct literature reviews to identify gaps

Get ideas for data analysis



Tip: Always involve a human and always disclose your use of the technology

*Exploring Digital
Approaches to
Address Suicide
Risk in Obstetric
Settings
R03 grant*

Email excerpt:

“The platform we use to host the intervention is called the Computerized Intervention Authoring System (CIAS), the terms and conditions are here:

<https://www.cias.app/termsandcondition>

Adaptive Testing Technologies (ATT) owns the CAT and scoring algorithms. The CAT is integrated into CIAS. The ATT privacy policy is

here: <https://adaptivetestingtechnologies.com/privacy-policy/>”

Applied to
Research?

Privacy Policy for Researchers

The Computerized Intervention Authoring System, v. 3.0 (CIAS) is committed to protecting personally identifiable information you and other users of this web application may provide us through our website. Please review the Privacy section of the Policy to understand how your personal information is collected, processed, and used. Please note that this Policy is for researchers and others who use the MSU CIAS Application to create content. You are responsible for obtaining appropriate informed consent and/or consent to terms of use and privacy policies from all participants or other end-users.

Please also note by using CIAS you are agreeing to the data practices described in this Policy.

The Personal Information We Collect

CIAS does not collect any personally identifiable information (“PII”) about you unless you

Ask GPT for a Summary

> CIAS Privacy Policy Summary 40 ▾

Review this privacy policy and summarize the data collection, storage, sharing and use practices and whether the practices pose risks or protections to potential research participants:
<https://www.cias.app/privacy-policy-end-users>

The CIAS (Computerized Intervention Authoring System) Privacy Policy for End Users outlines the platform's practices regarding data collection, storage, sharing, and use. Here's a summary of these practices and their implications for research participants: Cias +1

Data Collection

- **Voluntary Personal Information:** CIAS collects personally identifiable information (PII) only if users voluntarily provide it. This may include names, cell phone numbers, email addresses, and information related to health, feelings, safety, and health habits.
 - **Automatic Data Collection:** The system automatically gathers non-personal information such as IP addresses, browser types, visited screens, and session durations. This data is aggregated and not linked to individual users.
 - **Cookies and Web Beacons:** CIAS employs cookies and web beacons to collect anonymous, aggregated information to understand user interactions with the website. These tools do not track personal information.
-

Ask for a Plain Language Summary

You are a researcher responsible for conveying information about CIAS data management practices to potential research participants. In a 6th–8th grade reading level, provide a description of the factors that will assist a prospective research participant to make an informed and educated decision about their involvement in the research.

Here's a plain-language explanation of how the CIAS system handles your information, written to help you (or someone at a 6th–8th grade reading level) make an informed decision about joining a research study:

How Your Information Is Collected and Used in CIAS

We're using a computer-based system called CIAS to help with our research. Here's what you should know before deciding to take part:

1. What Information Is Collected?

- You may be asked to share **personal information**, like your name, email address, phone number, or how you're feeling.
- The system also collects **general information** like what kind of phone or computer you use, and what parts of the website you visit. This doesn't include your name or anything that can identify you.

2. Do You Have to Share Personal Information?

- No. You only share personal details if **you choose to**. That's called giving your consent.

3. How Is Your Information Kept Safe?

- CIAS uses tools to **protect your information**, like passwords and special codes.
- But, just like sending a regular email, there's **no 100% guarantee** that your data can't be seen by someone else. We do our best to keep it safe.

4. Who Can See Your Information?



Provide an infographic that will convey how personal health data is collected and managed by CIAS.

Ask for an Infographic

Image created

How Personal Health Data Is Collected and Managed by CIAS

 <p>What Information Is Collected? Personal information, you choose to provide, like your name, email, phone number, or feelings</p>	 <p>Is Sharing Personal Information Required? No, personal information is only collected if you choose to provide it.</p>
 <p>Measures are used to protect your data, but it's not possible to guarantee complete security</p>	 <p>Who Can See Your Information? Researchers and caregivers may see your information, with your permission</p>
 <p>What Happens to Your Information Later? Combined data may be used to improve the program and research</p>	<p>Consider Before Participating:</p> <ul style="list-style-type: none"> • Are you comfortable with the information being collected? • Who will have access to your data? • Do you have any security concerns?



Cartoon by Tom Chitty

Key Takeaways

The way research is conducted is changing fast.

It is never too early to think ahead and design digital health and AI studies to prevent downstream harms.

We can do this together, as a collective research community.

ReCODE Health Acknowledgements

