The Computing Research Association (CRA)'s Computing Community Consortium (CCC) and CRA-Industry (CRA-I) Response to the National Institutes of Health's Request for Information: Developing Consent Language for Research Using Digital Health Technologies

December 12, 2023

Written by: David Danks (University of California, San Diego), Haley Griffin (Computing Community Consortium), Tammy Toscos (Parkview Health), Katie A. Siek (Indiana University), and Pamela Wisniewski (Vanderbilt University)

This response is from Computing Research Association (CRA)'s Computing Community Consortium (CCC) and CRA-Industry (CRA-I). CRA is an association of nearly 250 North American computing research organizations, both academic and industrial, and partners from six professional computing societies. The mission of the CCC, a subcommittee of CRA, is to enable the pursuit of innovative, high-impact computing research that aligns with pressing national and global challenges. The mission of CRA-I, another subcommittee of CRA, is to convene industry partners on computing research topics of mutual interest and connect them with CRA's academic and government constituents for mutual benefit and improved societal outcomes.

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Below, we respond to all of the topics (each numbered and copied below in italics) solicited by National Institutes of Health's Request for Information. For each Component section except for Component 5, we also addressed gaps or additional concepts that should be included or clarified within the points to consider (roman numerals), as well as specific language proposed in the informed consent sample language (bullet points).

1) Utility and useability of this resource.
It is important to repeat that all parts of this guidance document may not apply to all projects and can thus be applied piecemeal, and to solicit feedback from people who are trying to operationalize the guideline. Without being prescriptive about how to ask your end-user about

their experience with the tool, we recommend looking for guidance from implementation science frameworks on your evaluation of the utility and usefulness. One example is the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework and the companion website[1] that offers a checklist that can help you think through the dimensions of providing a good tool.

2) For each component section, gaps or additional concepts that should be included or clarified within the points to consider (roman numerals)*, as well as specific language proposed in the informed consent sample language* (bullet points)*:*

1. ***Component 1: Introduction***
    a. *Gaps or additional concepts that should be included or clarified within the points to consider* (bullet points include specific language/recommendations we propose to address the gaps):
        i. **Who is responsible for paying for cellular data/internet connection.** This can be a significant unanticipated cost to the participant.
            - *As part of this study,* ***[insert expectation of who is responsible for cellular data/internet connection]****.*
                - ***[If participant is expected to pay]****: Participants must have their own* ***[cellular data/internet connection]****, to be eligible to participate in this study. We anticipate participants will use no more than* ***[data size (e.g., 1GB of data)]*** *of their* ***[cellular data/internet connection]****.*
                - ***[If researchers pay]:*** *The research team will provide* ***[describe how reimbursement will be provided (e.g., provide a check on the 1st Friday of each month to reimburse data costs; a separate phone with a paid data plan)].***
                - *[Depending on expectations of study data needs (e.g., if participants live in an area with limited connectivity)]: If you do not have access to* ***[cellular data/internet connection] [timing expectation (e.g., daily, all the time)]****, you should not agree to be in this study.*
        ii. **Inclusion/exclusion criteria.** The below lists are to be provided verbally to potential participants before they sign the consent form:
            - *Inclusion criteria for All Participants:*
                - *You have access to a usable Android or Apple smartphone.*

[1] https://re-aim.org/

- *You can download apps from your smartphone's app store.*
- *You have an accessible email address or are willing to set up an email account.*
- *You have a working phone with service with the ability to receive and send texts.*
- *You live in the U.S.*
- *You read, speak, and understand English.*
- *You agree to voice/video recording during interviews.*
- *You agree to consent to participate in the study.*

- *[If participants have an Android Smartphones only]:*
  - *You must have a Gmail account or be willing to set up a Gmail account.*
- *You will be excluded from the study if you meet the following criteria:*
  - *You do not fit into the inclusion criteria.*
  - *You have changed phone numbers more than twice in the past 365 days.*

iii. **What constitutes a "medical device" versus what does not.** Sometimes devices that don't serve a purpose related to medicine/treatment are inaccurately classified as medical devices.

- Per Section 201(h)(1) of the Food, Drug, and Cosmetic Act[2], a medical device is:
  "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

  (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being

[2] https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device

metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)."

- The FDA's Policy for Device Software Functions and Mobile Medical Applications[3] should also be referenced as a guide

iv. **Technology should not be treated as a monolith, and so more specificity and/or customization should be provided for each item.** For instance, there are significant differences with digital health data not collected through "devices", or digital health technologies like the following: Internet-connected/Not connected, Researcher owned/Third-party owned, Social Media/Internet of Things/Wearable/Virtual Reality, etc.

- *The health technology being used can be generally considered a form of **[add tech type (e.g., mobile app, virtual reality, sensor, wearable device)]**, which is **[give a general definition]**.*
- *The health technology **[is/is not]** an internet-connected device that **[will/will not]** store data on the cloud.*
- *The health technology was **[developed by the research team/developed by a third-party]** and the data will be stored and secured **[locally on the device/at the research site/by the third-party]**.*

v. **Describe how AI is used in the system.** Digital health technologies now include AI, but are not mentioned in this document. The draft document says "The resource does not address considerations for implantable devices, artificial intelligence, or other types of digital health technologies," but we believe that this document risks almost-immediate obsolescence if it fails to engage with "AI or other types of digital health technologies." For example, Epic's EHR currently has AI enabled communication from a physician. Thus, participants need to understand what communication is coming from a human vs. machine.

- A recommendation would be to create a taxonomy of different digital health technologies, so that recommendations can be made specific to those contexts. The FDA has done significant work in this space and has released a list of topics and their benefits and risks[4].

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[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications

[4] https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health

- The following are topics in the digital health field on which the FDA has been working to provide clarity using practical approaches that balance benefits and risks:
    - Software as a Medical Device (SaMD)
    - Artificial Intelligence and Machine Learning (AI/ML) in Software as a Medical Device
    - Cybersecurity
    - Device Software Functions, including Mobile Medical Applications
    - Health IT
    - Medical Device Data Systems
    - Medical Device Interoperability
    - Telemedicine
    - Wireless Medical Devices

2. *Component 2: Procedures*

a. *Gaps or additional concepts that should be included or clarified within the points to consider* (bullet points include specific language/recommendations we propose to address the gaps):

i. **Baseline competencies.** Researchers should create a brief training activity that participants complete to show they know how to use the device and who to contact if they have issues.

- *Before you start the study, the research team will ensure you can **[baseline activities (e.g., log in; add what you ate)]** with **[insert digital health technology name/type]***

ii. **Explainable AI.** How is data going to be transformed, cleaned, and processed?

- *We will clean the data by **[explain how data will be cleaned (e.g., removing information about you such as your location or IP addresses)]**.*
- *Our AI system will **[explain how data is processed (e.g., make suggestions based on your data, but we do not understand how the computer figures out those suggestions)]***
- *If you requested to have your data deleted, **[explain what data can be deleted, and the extent that the researchers have control of this process (e.g., your survey data can be deleted from university databases, however the 3rd party created application you use for diet management can only be deleted by the participant by contacting the [company and contact info])]***

iii. **Differentiate between treatment/intervention versus data tracking/monitoring.** Research could be either or both.
    - *In this study, we will use the information you provide to **[insert specific treatment/intervention] [insert and/or] [interest specific tracking/monitoring system]***

iv. **Different consent and other procedures for children** (e.g., Children Online Privacy Protection Act - COPPA[5])
    - *Given that the data collected will be from a minor under the age of **[insert relevant age]**, applicable regulatory laws **[insert name of applicable regulatory law (i.e., Children's Online Privacy Protection Act (COPPA) or Family Educational Rights and Privacy Act (FERPA))] will apply to this research**. **[Briefly describe the aspect of the law that is relevant to the participant]**.*

v. **Address "dark patterns" (e.g., Opt Out, nudges to consent) for obtaining consent for research as a prerequisite to receiving medical treatment.** Most patients don't realize they can opt out of research, so they may unknowingly be enrolled because they need medical care. This is a form of duress/coercement if patients believe that medical care could be denied without consenting to research. We recommend research teams investigate how participants are recruited and change enrollment to *opt in* instead of *opt out*.
    - *A research team is doing a study on [**insert study name/purpose**]. They would really appreciate you agreeing to share your [**insert data the team is collecting**]. Opt in by checking this box: **[insert blank check box]**.*

vi. **When parental consent is obtained for a minor, procedures and expectations need to be made clear to the minor at their literacy level throughout the study** (especially since they are not reading the consent form).
    - A simplified statement of the informed consent agreed to by the parent should be read to the child to communicate key points, such as they are not required and will not be punished in any way if they do not want to answer any questions or decide they no longer want to take part in the study.

[5] https://www.ecfr.gov/current/title-16/chapter-I/subchapter-C/part-312

3. ***Component 3: Data sharing and ownership***
    a. *Gaps or additional concepts that should be included or clarified within the points to consider* (bullet points include specific language/recommendations we propose to address the gaps):
        i. **A tractable and understandable list out what data is tracked.** We acknowledge that sometimes there is a vast list of data tracked, but an itemized full list, if feasible, or at least a summary accompanied by an easily understandable visual, would be ideal. For example, location while using app/location while not using app.
            - For example, instead of "*You will be asked to share **[insert types of data]** via **[insert digital health technology name/type] [insert frequency (e.g., at random intervals throughout the day, daily, weekly)],"*** we recommend:
            - *You will be asked to share:*

Data Type	**Frequency**	**Who has access to the data**
Your location when carrying ***[insert digital health technology name/type]***	When using app	-Research Team -Phone* -Cellular provider*
Movements you make with ***[insert digital health technology name/type]***	All the time	-Research Team -Phone*
X Posts	All the time	-Research Team -X*

            - * data is available to these groups independent of the study
        ii. **Language regarding whether and how the data is protected by HIPAA *(see Appendix I for an example).*** This is critical for any scientist whether or not they are in a health system.
            - Sample language from NIH can also be found here[6].
        iii. **Researchers should consider obtaining a NIH Certificate of Confidentiality[7] to protect participant data from legal discovery.**

[6] https://privacyruleandresearch.nih.gov/authorization.asp
[7] https://grants.nih.gov/policy/humansubjects/coc.htm

- "Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except with the subject's consent or in a few specific situations. Researchers with a CoC may disclose identifiable, sensitive information ONLY in the following circumstances: 1. If required by other Federal, State, or local laws, such as evidence of child abuse or a subject's threatened violence to self or others; or 2. for the purposes of scientific research that is compliant with human subjects' regulations Researchers with a CoC must ensure that anyone who is conducting research as a sub-awardee or receives a copy of identifiable sensitive information protected by the policy understands they are also subject to the disclosure restrictions."

iv. **Participants should be informed of how inferences (e.g., machine learning classifications) from the data may be used/shared.** In general, inferences about potential medical information (e.g., use of AI to predict potential cancers) are not automatically treated as private health information within US law. We propose instead that inferences to personal information should be treated as actual personal information, as is done in the California Privacy Rights Act (CPRA).
    - *The data that you provide will be used to make inferences and predictions about **[insert targets]**. These inferences will be protected in the same ways that we protect your original data.*

v. **It is unreasonable to expect participants to read and digest the Terms and Conditions of an organization.** Terms and Conditions are usually not at an 8th grade level or understandable. If they are relevant to the study, the onus should be on the researcher to summarize them at an 8th grade reading level.

vi. **Explicitly note what data participants can ask to be removed and what data they can not.**
    - *You may stop participating in the study at any time. If you want the data we previously collected to be removed from the study, **[insert details about what researchers are able to remove and emphasize that they will remove as much as they can]**.*

vii. **Make it explicit that participants do not own 3rd party data.**
    - *The research team does not own the data you supply on **[insert social media platform or application name]** and therefore can not*

guarantee *how it will be* ***[e.g., used, stored, retained after deletion].***

viii. **Portability of the data** - Can participants request raw data and/or synthesized reports based on their data for their own benefit? If so, researchers should provide details about how participants can obtain the data.

- *Participants* ***[insert can/cannot]*** *request raw data for their own benefit. Also they* ***[insert can/cannot]*** *request synthesized reports based on their data for their own benefit.* ***[Insert details on how participants can obtain their raw data and/or synthesized report].***

4. ***Component 4: Potential risks***

a. Gaps or additional concepts that should be included or clarified within the points to consider (bullet points include specific language/recommendations we propose to address the gaps):

i. **Risks related to child mandated reporting status of the reseachers** (e.g., child abuse, sexual abuse, imminent risk of harm).

- *If data collected from this study strongly indicates that you are at serious risk of physical injury, sexual abuse, mental injury, or physical neglect, we are required by law to report these types of imminent risks to the proper authorities.*
- *The data collected during this study will not be monitored on a daily basis, so this study should not be considered as a form of real-time screening or reporting.*
- *As mandated reporters, if we have reasonable suspicion that a child has been abused, neglected or threatened of harm in the state, we will contact the state hotline to report the incident. The Hotline counselor will determine if the information provided meets legal requirements to accept a report for investigation.*

ii. **External and unbiased point of contact in case of harm**. There should be a trustworthy individual documenting perceived harms that does not have a stake in the success of the research. Oftentimes, a participant's only option is a researcher or an “advocate” that is funded by the Research Institution. If there is not an option for an external individual, at minimum the priorities of the individual they are being asked to report to should be transparent from the beginning.

- *If you feel like you are being harmed in any way by this study, [****insert title and contact information for an individual that they***

can reach out to, including information on who is funding this person's consulting and what their priorities are*].*

iii. **Proactive detection.** Participants should know if they are going to be notified if there is bias/harm during or after the study.

- *The research team is monitoring the data collected for bias/harm throughout the study, and will continue to do so after it is complete. If you are ever negatively impacted by [**insert type/s of harm that they could experience**], and the research team finds out, you will be notified within [**insert amount of time**].*

iv. How to handle emotional distress.

- *If you become emotionally distressed and feel you need help, you can speak to your physician to ask for local resources or a local counselor. You can also call 211 or go to http://www.211.org/ to find the resources you need. If you need immediate help, you should call 211. The following are also available to you 24/7 to contact: National Parent Helpline 1-855-427-PARENT (2736); SAMHSA's National Helpline 1-800-662-HELP (4357); and National Suicide Prevention Lifeline 1-800-273-8255.*

6. Component 6: Cost

b. *Gaps or additional concepts that should be included or clarified within the points to consider:*

i. **Clarity on responsibility for costs associated with potential risks of the intervention**

ii. **Clarity on the cost for internet/cellular data access**. Expectation of the amount of data the participant is expected to supply. Impact on overall bandwidth.

7. Component 7: Withdrawal

c. *Gaps or additional concepts that should be included or clarified within the points to consider*:

i. **Should be more clear that unless they physically are not able to figure out which data is yours, you can discontinue your involvement (including your data) at any time.**

ii. **Whether data will be destroyed completely or retained without analysis based on data retention laws in the state.**

iii. **When parental consent is obtained for a minor, it needs to be made clear to the minor during the study that they are allowed to**

withdraw/not answer at any time (since they are not reading the consent form).

iv. **Clarify that withdrawing from the study may not be the same as withdrawing the data already collected from the study.**

v. **Explicit the participant vs. researcher responsibility for deleting data** (in consent form at beginning and/or handout later).

vi. **Clarify that the research team may withdraw them from the study if the participant no longer qualifies** (e.g., no longer has a phone, data plan, etc.). This could also be the case if the research team identifies someone as fraudulent (e.g., a mobile study where people in the United States are participating, but the participant location continues to indicate they are in another country and have not disclosed international travel) ;

vii. Explain that withdrawal will not adversely impact their standard medical care as provided prior to entry into the study.

3) Hurdles or barriers to wider use of this resource by the community.
Table of Contents are very rarely at an 8th grade reading level, so it is problematic if consent language is outsourcing at all to Table of Contents. There should be a positive obligation on researchers to give 8th grade level summary, visuals, etc.

4) Other feedback relevant to this resource.
Sometimes template language like this can manifest into required protocol without care being put into making sure it works for the study, and it is important to not require it as a blanket statement if it does not apply directly to the research.

Appendix I: HIPAA Authorization Sample Language

Federal law provides additional protections of your medical records and related health information.

I agree to permit the Principal Investigator, ***[name]****, and research staff ("Researchers"), and* ***[research organization]*** *may use and disclose health information that identifies me for the purposes described below. I also agree to permit* ***[health system name]*** *and its affiliates, my doctors, and my other health care providers may disclose health information in my medical records to the Researchers and* ***[research organization]*** *for the purposes described below.*

1. The health information that may be used and disclosed includes: all information collected during the research described in the Informed Consent Form; and health information in your medical records that is relevant to the research described in the Informed Consent Form.

2. The Researchers may:

- *use and share my health information to conduct the research;*
- *disclose my health information to the sponsor of the research,* ***[research organization]*** *and its agents;*
- *disclose my health information to* ***[health system name]*** *and its affiliates;*
- *disclose my health information as required by law;*
- *disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research; and*
- *remove from my health information my name and other information that could be used to identify you.*

3. Study Sponsor may:

- *use and share my health information to conduct the research;*
- *use my health information as described in the Informed Consent;*
- *disclose my health information as required by law;*
- *disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies, and the conduct of research; and*
- *remove from my health information my name and other information that could be used to identify me.*

4. Once information that could be used to identify you has been removed, the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and [research organization] as permitted by law.

5. Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure. However, the Researchers and ***[research organization]*** *agree to protect your health information by using and disclosing it only as permitted by me in this Authorization and the Informed Consent. Also, no publication about the research will reveal my identity without my specific written permission. These limitations continue even if I revoke (take back) this Authorization.*

6. Please note that:

- *You do not have to agree to this Authorization, but if you do not, you may not be allowed to participate in the research.*
- *You may change your mind and revoke this authorization at any time. To revoke this Authorization, you must write to* ***[principal investigator name and address]****. However, if you revoke this Authorization, you may no longer be allowed to participate in the research. Also, even if you revoke this Authorization, the information already obtained by the Researchers and* ***[research organization]*** *may be used and disclosed as permitted by this Authorization and the Informed Consent.*
- *While the research is in progress, you will not be allowed to see your health information that is created or collected in the course of the research. After the research is finished, however, you may see this information as described in* ***[health system name]*** *Notice of Privacy Practices.*

7. This Authorization will expire 50 years from the date of signature.