Response to Request for Information on the NIH “Developing Consent Language for Research Using Digital Health Technologies"

Notice Number: NOT-OD-24-002

Key Dates

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Policy

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-002.html

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Response

1. **Utility and useability of this resource.**
   - This is an impressive resource with a comprehensive list of considerations.
   - We appreciate the caveats that other issues need to be considered and this language alone is not sufficient. Also appreciate the guidance to align the consent with their Data Management and Sharing Plans.
   - Template language is useful, but does not cover all the really important points mentioned in the “key points” to consider. Consider better aligning the sample language with these points (e.g. having more samples or more specific examples). The sample language is likely to be used without necessarily consulting all the points above.
   - Since data sharing is expected and repository information is prompted, we would encourage discussion and sample language around potential future uses of the research data.
   - With the goal of providing a resource that is equivalent to an 8th grade reading level, adjustments might be made to the overall length, technical language, and mentions of “terms and conditions” throughout the sample language. We are concerned that the length and some of the technical language might cause participants to disengage from

the consent process, particularly in the Risks section. We also have concerns that the "terms and conditions" may not be fully understood by the PI, and therefore, would not be understood by the participants. Potential recommendations could be the PI interprets the terms and conditions for participants with the guidance of general counsel, and/or recruit participants who are already using the devices, who have already clicked through the terms and conditions on their own.

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

Component 1: Introduction

- Concerned about PIs not knowing the specifics around proprietary tools and the relevant data ownership/privacy aspects. Is this the responsibility of the PI to read, understand, and distill down into an 8th grade reading comprehension for participants? Would they even have licenses to re-share the data collected on a commercial/proprietary device?
- These points are noted in the "points to consider" but there is no sample language to address them. We would like to see sample language that covers these points.

Component 2: Procedures

- Recommend emphasizing the general way participants will access/collect data from the device, but NOT including the technical details in the consent document. This would make the consent very long to read and distract from important information about how their data will be used. Additionally, the specific steps may change as technology updates and changes.
- Recommend including specific sample language calling out the "passive information" that will be collected and identifiable. PIs should understand the data that will be collected on participants.

Component 3: Data sharing and ownership

- The sample language suggests including data sharing information, which we deeply appreciate. The sample language prompts "basic summary information about the repository," and we encourage NIH to specifically include characteristics to describe in the consent, such as the specific repository, restricted versus open access, data to be shared versus withheld, and de-identification processes.
- The sample language suggests notifying participants that the commercial device company will have access to the data, and may retain the data with no control from the research team regarding protection of the data or privacy. This is concerning language and will likely alarm participants. The recommendation may be that PIs clearly understand the company's policies and share with study participants.

Component 4: Potential risks

- We recommend that the sample language around data breach and re-identification risk be more specific (e.g., what is being done to protect their identities and why is there still

a risk involved). Language further down in the sample consent is a sufficient replacement for this vague beginning: “By using…there is a risk you may be identified as a study participant. This may occur if the…is lost, misplaced, or stolen. It may also occur if your identity and information recorded in the…is otherwise accessed by another person.”

Component 5: Potential benefits

- none

Component 6: Cost

- none

Component 7: Withdrawal

- none

3. Hurdles or barriers to wider use of this resource by the community:

- Local institutions likely have their own IRB templates, and it may be difficult for PIs to align this content with the recommended (and required) language in their institutional templates. We encourage NIH to connect with institutional IRB offices to recommend integrating this language with local templates and recommendations.
- We'd like to reiterate a point made in #1 regarding the terms and conditions that come with third party contractors. It is unlikely these are at an 8th grade reading level and it is burdensome to the PIs to completely understand and translate these terms. However, we do applaud the efforts at transparency by bringing up other contracts and terms the participant may be agreeing to while participating in this study.

4. Other feedback relevant to this resource:

- none