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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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Submitted through: Comment Form: Developing Consent Language for Research Using Digital Health Technologies - Office of Science Policy (nih.gov)

December 12, 2023

NIH Office of Science Policy
6705 Rockledge Drive, Suite 630,
Bethesda, MD 20892

RE: UC Comments in Response to NOT-OD-24-002, NIH's Request for Information: Developing Consent Language for Research Using Digital Health Technologies (Response Date: December 12, 2023)

To Whom It May Concern:

I write on behalf of the University of California (UC) system regarding the NIH's Request for Information on Developing Consent Language for Research Using Digital Health Technologies (DHT) issued on October 11, 2023.

The UC system – comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories – stands at the forefront of cutting-edge research and technology development. As a system, UC receives approximately $7 billion annually of extramural awards to support research conducted throughout all UC locations. UC generally receives five to six percent of the NIH annual appropriations for research.

1. Utility and useability of this resource

UC appreciates NIH's recognition of the Institutional Review Board's (IRB) duty and aptitude for providing input on consent language. Consent language varies based on the nature of the study, the data collected, the research participant population, and any local considerations. The IRBs are best positioned in recommending language in consent forms for each particular study, so we appreciate NIH maintaining that the use of the NIH sample language is voluntary.

In response to NIH's RFI, UC's overall concerns with the proposed sample language is the following:

1) Length and readability of the sample language;
2) Inclusion of information beyond the scope of informed consent; and
3) Inclusion of content beyond the responsibility of researchers.

The sample language NIH provided is two pages in length. The two pages does not account for the information researchers would add to the sample language that would be specific to their study or health technology. We ask that NIH modify the sample language altogether for length.

Additionally, per the Revised Common Rule, informed consent should be concisely drafted at no higher than an 8th grade reading level. The Flesch-Kincaid grade level for the sample text (before researcher additions) is at the 11th grade reading level. If the intent is to be clear and accessible, then lower reading level language should be used. Lengthy informed consent documents can be a deterrent during participant recruitment, so we suggest more concise and easily readable sample text.

We recognize though that NIH is requesting specific feedback on the components identified in the RFI. Below we provide the feedback to each component.

2. Feedback on Each Component Section
Component 1: Introduction

- Component 1 appears similar to the "Key Information" section required by the Revised Common Rule. The information is duplicative of what would typically be a part of the "Key Information" section in a consent form and increases the length of the informed consent. We ask that NIH clarify the intent of Component 1.

- Component 1 states, "Provide explanation around what it means to be proprietary technology and how it may determine who owns or has access to or rights to distribute the data…" However, in Section III the RFI states "This resource does not address future use of data collected from digital health devices." These statements seem to be at odds with one another, so we request NIH clarify whether these are not mutually exclusive concepts or remove one of the statements. UC strongly advocates omitting from the guidance information regarding future use of data collected from DHTs as it is not a mandatory component of the informed consent, as prescribed by the Revised Common Rule, and institutions may have more suitable formats to present this information to participants.

Component 2: Procedures

We suggest removing the recommendation to explain the legal terms of use and provide a technology tutorial for use of the DHT to research participants. We believe that these topics do not belong in an informed consent because they do not explain risks and benefits of the research to participants in the study. We propose removal of both the guidance and the sample language to avoid confusing researchers as to what the required and appropriate content is for informed consent forms.

Component 3: Data sharing and ownership

UC recommends removing the information in the second bullet that directs researchers to educate participants on whether the data collected by the DHT is owned by the company, whether the data may be sold or shared to third parties without explicit participant consent, and to inform participants of end user agreements, terms and conditions, and terms of service. This information is not related to the risks and benefits of participating in the research. Adding this type of language to an informed consent is overly technical, doesn't further enhance protections over subjects, and may be beyond the scope of the researcher.

Component 5: Potential benefits

The sample language in Component 5 appears to advocate for a separate benefits statement related to the use of DHT. Since the Revised Common Rule already requires a benefits statement, we recommend NIH delete the sample language here or provide sample language that combines the potential benefits of study participation overall. Duplication will increase the length and complexity of text required to be read by participants, which can lead to complications with recruitment.

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

UC appreciates NIH's efforts to provide guidance and sample language that is not mandatory. However, we are concerned that the sample language can be interpreted as an authoritative reference for researchers. If all researchers begin using a lengthy and complex template without regard to what is appropriate to their study, participants may find the content too complex or time-consuming and there may be negative repercussions for study recruitment and retention. Additionally, because the sample consent expands the scope beyond what is traditionally included by researchers, there is a risk of inaccuracy of information. While the information recommended may be relevant to the study, such information may be best provided by another subject matter expert at the institution and outside the informed consent. Given the complexity and the variation in developing informed consent, we recommend that NIH remove the sample language and simply provide the guidance.

4. Other feedback relevant to this resource:

- We are happy to see the NIH note the requirement of data management and sharing plans and that researchers should ensure alignment of data management and sharing plans with informed consent language. We ask that NIH take this one step further and emphasize that PIs prepare protocols and IRB applications that are consistent with the data management and sharing plans. Because researchers must submit their data management plans far in advance of their development of informed consent language or their human subjects protocol, further reminders that researchers ensure alignment would be appreciated.

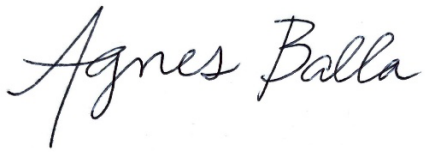
- We note in the Key Points, NIH states this consent resource does not address future use of data collected from DHTs, which may have additional considerations when developing or

reviewing informed consent. UC interprets this to mean that NIH is not intending this language to meet the broad consent requirements.

- The sample language throughout the document includes places for insertion of the DHT's name. Numerous insertion points lead to a greater possibility of mistakes, particularly in templated language. UC proposes removal of multiple insertion points in the sample language and replacement with a sentence such as "In this study we will be using a piece of technology called [insert name]. In this consent form we will refer to this as the study's "digital technology.""

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue. If you have any questions concerning these comments, please contact Ruchika Dhussa, Senior Research Policy Manager, at Ruchika.Dhussa@ucop.edu.

Sincerely,



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