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September 29, 2021

NIH Office of Science Policy
Office of the Director
Division of Clinical and Healthcare Research Policy

RE: UC Comments in Response to the NIH Request for Information: Developing Consent Language for Future Use of Data and Biospecimens (NOT-OD-21-131)

To Whom It May Concern:

I write on behalf of the University of California (UC) system with regard to the NIH Request for Information (RFI): Developing Consent Language for Future Use of Data and Biospecimens (NOT-OD-21-131) issued on July 1, 2021.

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately $6 billion annually of extramural awards to support research conducted throughout all UC locations, and generally receives five to six percent of the NIH annual appropriations for research.[1]

UC values the importance of properly seeking consent from those participating in research, and to account for ways in which sharing of data and biospecimens impacts the consent process. We appreciate the NIH's work in developing guidance and sample consent language to support future data and biospecimen sharing. While the sample consent language is presented as voluntarily used by the community, we are concerned that over time this language will be expected to be universally adopted by the research community, diminishing the ability for the consent process to remain flexible to account for study variations, needs of specific participant populations, and local requirements. We strongly suggest that instead of providing sample language to the community, that the NIH focus on guidance only. If the NIH does move forward with issuing sample consent language, we recommend that the NIH: 1) clarify whether the RFI's objective is to meet the requirements of broad consent, and 2) avoid including an opt-out option for future data or biospecimen sharing under *Section IV, Component 2*. In addition, UC suggests that the NIH provide an explanation on applicable laws and regulations in the *General Points to Consider* section. These points are specified below.

[1] University of California Accountability Report 2021: https://accountability.universityofcalifornia.edu/2021/chapters/chapter-9.html

Utility and Usability of Sample Consent Language

Forgo Sample Language and Provide Guidance Only

On a regular basis and by their regulatory authority, Institutional Review Boards (IRBs) successfully provide input on consent language, which can vary depending on the nature of the study, the data or biospecimens collected, the research participant population, and any local requirements. Their experience and expertise allows them to account for differences in consent language to best protect human subjects and continue important research. To encourage flexibility and the appropriate exercise of IRB discretion, UC recommends that the NIH retract the sample language provided in this RFI and issue guidance instead. The NIH could flesh out the *General Points to Consider* section by providing evidence-based guidance on what IRBs should contemplate when considering consent language for future data and biospecimen sharing. The NIH could also include guidance on the NIH's interpretation of broad consent requirements, as described further below.

Gaps or Additional Components that should be Included

Clarify the RFI's Objective regarding Broad Consent

UC is unclear whether this RFI is meant to address the requirement in 45 CFR 46.116(b)(9) regarding the future use of deidentified data or biospecimens or if it is meant to move the community towards using broad consent for future use of identifiable data or biospecimens. *Section II, Instructions for Use* describes identifiable data and biospecimens obtained for primary research implying that 45 CFR 46.116(b)(9) is at play, but the RFI subsequently discusses sharing data and biospecimens for future research without noting whether the information should be deidentified, such as in *Section IV, Component 1, Sample Language.* This creates confusion as to whether the RFI's intended goal is to address broad consent requirements in 45 CFR 46.116(d). If the NIH wants to address broad consent in the RFI, then it should be clear about this objective so that the sample language could be reviewed in that light. UC suggests that if achieving broad consent is NIH's objective, then it would be helpful to have guidance on NIH's expected requirements and subsequent application of using broad consent (such as, what are the implications if research participants say "no" to a study or "no" to the opt-in option for future research with the data or biospecimens from the current study; can they be asked to participate in other studies; what actions need to be taken if participants opt out later and how far back should an institution look to apply a participant's "no"?).

Specific Language Proposed in the Informed Consent Sample Language

Section IV, Component 2: Voluntary Consideration

IRBs are well trained in ensuring that consent language is not coercive or unduly influential, however the first and second bullets collectively in the *Considerations* section seems to imply that having an opt-out option for any future data or biospecimen sharing is the best way to prevent coercion. UC recommends that the NIH provide a more balanced explanation of why certain studies may not be able to offer an opt-out option.

Further, UC recommends that the NIH avoid including an opt-out option for future data or biospecimen sharing. Instead a well-developed consent process should explain the risks and benefits of data/biospecimens sharing and participants should be able to decide whether the study is right for them. Otherwise, the language included within the opt-out option should be explicit regarding the inability to "un-share" previously shared information. Lastly, the opt-out option does not align with the values of the NIH's data sharing policy, which emphasizes the importance in using already collected information and biospecimens.

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

Applicable Laws and Regulations

Applicable laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and an abundance of state privacy laws, impact language in the consent form. Also, FDA-regulated clinical investigations are subject to specific FDA regulations and guidance regarding informed consent. UC strongly endorses the comment provided by the Council on Governmental Relations (COGR) to include the following text as part of the *General Points to Consider*:

> A variety of national, state, and/or local laws, regulations, and policies (collectively "Laws") may apply to the research, and these Laws may impact the nature and content of the informed consent process and documentation. Before using any of the sample language, persons responsible for the study should consult appropriate legal counsel and IRB contacts to determine which Laws apply to the research, whether the sample language conforms to those Laws, and how those Laws otherwise affect the consent process and documentation. [*Additional text to be added if FDA clinical investigations fall within the scope of the RFI*: Importantly, clinical investigations of FDA-regulated articles have their own informed consent requirements that must be considered.]

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination
University of California, Office of the President