PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

September 7, 2021

Lyric Jorgenson, PhD
NIH Office of Science Policy
OD/Division of Clinical and Healthcare Research Policy

Via email: lyric.jorgenson@nih.gov

RE: NOT-OD-21-131: Request for Information: Developing Consent Language for Future Use of Data and Biospecimens

Dear Dr. Jorgenson,

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Office of Science Policy's Request for Information on Developing Consent Language for Future Use of Data and Biospecimens, published July 1, 2021.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of biomedical, behavioral, and social science research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community, including members and staff of human research protection programs and institutional review boards (IRBs), investigators, and their institutions. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

PRIM&R appreciates the NIH's effort to assist investigators and IRBs with developing informed consent materials for data and biospecimen sharing. As data and biospecimen sharing become the norm, institutions, investigators, and IRBs may benefit from having access to sample consent language that is simple and comprehensive. However, we believe the proposed resource would be more useful to relevant stakeholders if it was clearer in its **scope** and **force**, and if it **provided additional language explaining the broad context for data sharing**. We elaborate on these points, and provide some additional suggestions on specific provisions of the document, below.

Scope. It is not clear whether the proposed points to consider and sample consent language are intended to apply only to *deidentified*

information and biospecimens, or to include *identifiable* information and biospecimens. Section II says, "This resource consistently refers to 'data and specimens' as a means to capture all *identifiable information and biospecimens* that research participants may contribute as part of a research study" (emphasis added), but the sample language provided later in the document is inconsistent. **Component 1: Introduction-Description** seems to deal only with deidentified information and biospecimens (per the definitions of deidentified in the Common Rule). However, in **Component 4: Risks and Benefits**, under the consideration of risks, the RFI mentions sample language that should apply if the key code will remain with the biospecimen or data during storage and sharing, a possibility not mentioned in Component 1. Furthermore, from the perspective of protecting the rights, privacy, and information of research participants, it is considered best practice *not* to keep key codes with stored biospecimens or data; rather, if recontact with participants is necessary, secondary researchers should contact the researchers who collected the materials or data and have access to the code, and have them reach out to participants.

Clarifying the scope of this resource is important because studies to which this sample language would be relevant are presumably subject to the Common Rule. Yet as written, it is not clear how the recommendations in this document relate to the provisions of the Common Rule. For example, the Common Rule introduces broad consent, a new regulatory mechanism for storage and future research use of identifiable information and biospecimens. What is the intended relationship is between the NIH's suggested language for consent and the requirement for regulatory broad consent? With respect to identifiable biospecimens and data, is the template language provided intended to be consistent with regulatory broad consent? It certainly is not a full broad consent template, as it leaves out many components of broad consent (45 CFR 46.116(d)). In any case, it would be helpful for the document to clarify its relationship to broad consent as codified in the Common Rule, and whether and how this language could (or could not) be used to meet the broad consent requirements.

In addition, the Common Rule allows researchers to strip identifiers from data and biospecimens collected during a primary research study and make them available for future research without seeking informed consent, since research with such data and specimens is not considered human subjects research. The Common Rule requires only that potential participants be informed about this possibility (45 CFR 46.116(b)(9)(i)). In this document, **Component 2: Voluntary Participation**, on the other hand, NIH seems to be recommending that participants be given the opportunity to provide their informed consent for any scenario in which their data or biospecimens might be stored or shared for future research, even if identifiers will be stripped before doing so. If NIH considers seeking informed consent in all cases a best practice—even though it goes beyond regulatory requirements—then it should make that explicit, and, furthermore, should initiate a conversation with the stakeholder community about why this is a best ethical practice prior to inserting such language into a template tool.

***Force*.** Related to this last point, the RFI states that the use of the sample language provided is "completely voluntary." However, it is reasonable to expect that NIH-funded entities will not see use of this language as optional, but rather will interpret the guidance as a mandate

regarding what must be included in informed consent materials for data and biospecimen storage and sharing from studies funded by NIH. The NIH should therefore be clear about whether this document is establishing NIH policy, especially given that, as noted above, NIH's language seems to go beyond the regulatory requirements of the Common Rule. Again, if NIH is seeking to make policy, then we urge it go through normal policy-making channels rather than establishing *de facto* policy in tools such as these consent templates.

Broader context on value of data sharing. Additionally, this resource would be more useful to the community if it included general language providing the context for the request to share data, for instance, why data sharing is valuable, how it contributes to science and knowledge, why participants are asked to share their data, and the like. As it is currently written, whether participants allow their data or biospecimens to be shared is set up as a purely "neutral" choice with little explanation of how contributing information for future use can advance science. As a leading proponent of responsible data sharing and its value to the scientific enterprise and the public, NIH has an opportunity to shape how data sharing is introduced and presented to potential research participants across a wide range of studies. We strongly encourage NIH to embrace this opportunity and provide its stakeholders with template language that explains the value of data and biospecimen sharing. A helpful example of such language can be found in the Secretary's Advisory Committee on Human Research Protections' (SACHRP's) broad consent template: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-d-august-2-2017/index.html.

In addition to these broad concerns, PRIM&R has the following comments on specific portions of the document:

- Section II, "Instructions for Use" would be improved if it provided clearer guidance on *when* this sample language should be used. The document acknowledges that "Not all of the components will be appropriate for every informed consent form"; the stakeholder community would benefit from more explicit guidance from NIH regarding when studies merit the inclusion of some or all of this language.

- **Component 1: Introduction-Description**, Option #1: The sample language here should make clear that the code is not shared along with the biospecimens, and is safeguarded by the original researchers who have obtained consent.

- **Component 1: Introduction-Description**, Option #2: The sample language should be rewritten to make clear that, even when all reasonable steps are taken to remove identifying information, deidentification cannot be guaranteed, given advances in technology and the ways in which various set of "deidentified" data can now be combined. Understanding this risk is a critical component of informed consent to participate in the main study.

- **Component 3: Discontinuation/Withdrawal** states that, in the case of discontinuation or withdrawal, "We will do our best to retrieve all your data and

biospecimens that have already been shared, but it may not be possible." This language runs the risk of overpromising the retrieval efforts that study teams are prepared and equipped to make. We recommend instead that the default here be a statement that if participants request that their date no longer be shared, researchers will not keep sharing the data and biospecimens, but that data and biospecimens that have already been shared cannot be withdrawn.

Finally, we would like to use this opportunity to make a broader point, namely, that there remain significant, unanswered policy questions regarding how researchers and funders can best address future research with data and biospecimens in way that enhances, rather than undermines, public trust, especially when it is no longer possible for data to be "deidentified." The mechanism of informed consent is critical to (re)building trust in research, but it is not the only means of doing so. We encourage funders and policymakers like the NIH to address head on the full range of issues that are crucial to public trust—including data governance and stewardship, researcher responsibilities, privacy protections, considerations of equity, the data sharing context for vulnerable populations, and notions like the "public good," to name a few—rather than focusing narrowly on informed consent.

We hope our comments on the current draft will be useful as you further develop this resource. Thank you again for the opportunity to comment and for the NIH's work on this important issue. Please feel free to contact me at 617.999.4422 or ehurley@primr.org if we can be of any further assistance.

Sincerely,

Elisa A. Hurley, PhD
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors