September 29, 2021

NIH Office of Science Policy
Office of the Director
Division of Clinical and Healthcare Research Policy
6705 Rockledge Drive
Suite 750, Bethesda, MD 20892

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

Dear Dr. Collins,

On behalf of the Cystic Fibrosis Foundation, we are writing to provide comments on the National Institute of Health (NIH) request for information titled Developing Consent Language for Future Use of Data and Biospecimens. We appreciate the opportunity to provide commentary on this important topic and commend the NIH for seeking input from stakeholders to refine the language included in the data sharing consent forms. We hope the comments we have provided below may add to the NIH's ability to foster a greater sense of participants' autonomy and trust in biomedical research and increase enrollment and representation of underrepresented minority groups in biomedical research.

Background on Cystic Fibrosis and the CF Foundation
The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis (CF) – a rare genetic disease that affects more than 30,000 people in the United States. The CF Foundation has been engaged in virtually every element of the research and development process. The Foundation's Therapeutics Development Network (TDN) is the largest CF clinical trials network in the world. The TDN consists of 92 clinical research centers across the US and supported more than 60 multicenter trials in 2018 alone.

Cystic fibrosis affects many people of different racial and ethnic backgrounds. However, for many years there has not been adequate representation of people of color shared in the stories and descriptions of the disease by medical and public health entities, as well as by the CF Foundation and the CF community. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within these groups is critical to the Foundation's mission of serving all people with CF.

Clarifications Regarding the Sample Language
The sample language provided is a useful foundation for guiding institutions and researchers; however, there are several areas that could be clarified. In Component 1 where the sample language states, "*To use your data and biospecimens, researchers must get approval and they must agree not to try to identify you,*" explaining who grants approval (an Institutional Review Board) and what approval means may be beneficial. Likewise, in the following paragraph of Component 1 that states, "*The code key can*

only be accessed by people who have permission," we suggest that the sample language explains that those who have permission also receive training and are required to protect the participant's identity. Furthermore, when explaining to the participant that they can opt out of sharing their data, it is important to include language that is very clear about the consequences of withdrawing from the study means. For example, fully explain the different levels of contribution, whether that is full removal from the study or if the participant is still part of the study but not donating the specimen. We support the sample language in Component 2, as it provides clear and concise parameters.

Similar to Component 2 of the Sample Language, Component 3 should include two options: when opting out of sharing data and biospecimens is optional and when it is not optional. If there are more components to the study beyond data and biospecimen sharing, the participant should be aware that they may still be included in the study, even if they opt out of sharing their data or collected samples. In instances where data and biospecimen sharing are not optional, it must be made clear to the participant that withdrawing from the study or choosing to opt out at a later time means they are leaving the study entirely. In any case where the participant opts out of sharing their data or biospecimens, it should be made clear to them that their data and biospecimens will be destroyed; this may reassure those who are untrusting of clinical trials.

Points to Consider
Language barriers can significantly reduce the enrollment rates of underrepresented minorities in biomedical research studies. To encourage participation from underrepresented minorities, providing the biospecimen and data sharing consent forms in a range of commonly spoken languages may support diversity in research studies by ensuring that they are fully informed, and information is communicated most clearly to the individual. It could be beneficial to engage focus groups of underrepresented minorities to provide feedback on the sample language and most accurate translations. Within the focus groups, it would also be pertinent to seek feedback regarding the "points to consider," especially as it relates to mistrust of the medical and research community, which is a significant barrier for many individuals to feel comfortable participating in biomedical research.

It is important to communicate clearly to participants that while their biospecimens may undergo further testing, they will not be informed of any results as the use of their specimens is for research purposes only. Genetic research is a unique situation that many participants, particularly those belonging to historically marginalized communities, may feel uncomfortable participating in, and the use of their biospecimens should be clearly explained. For example, including language such as, "Future investigators may use the samples collected as a part of this biorepository for whole genome sequencing, which involves mapping all of your DNA. This is a powerful approach that can lead to new discoveries that are not possible when only certain genes are studied. However, these studies might uncover a genetic abnormality that you did not previously know about or it may uncover that family members are not biologically related to each other in the way expected. If future investigators uncover such information, they will treat it confidentially and will not disclose it to you or anyone else outside of that investigator's research team."

Conclusion
Once again, we commend the NIH's efforts to create a resource of sample language and best practices for investigators wishing to tailor their data and biospecimen sharing consent forms in a manner that supports study participants' autonomy and increases their trust of the medical and research community. Given the importance of increasing diversity and engaging individuals from underrepresented minority

groups in biomedical research, including in cystic fibrosis research, we thank you for the opportunity to comment and are eager to further support the NIH's efforts on this topic.

Sincerely,

Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation